EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY IN SELECTED CANCER CENTERS AT ERODE.

A DISSERTATION SUBMITTED TO
THE TAMILNADU DR. MGR MEDICAL UNIVERSITY,
CHENNAI, IN PARTIAL FULFILLMENT OF THE
REQUIREMENT FOR THE DEGREE OF MASTER OF
SCIENCE IN NURSING
2009 – 2011

A STUDY TO EVALUATE THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG

HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY IN SELECTED CANCER CENTERS AT ERODE.

APPROVED BY DISSERTATION COMMITTEE ON _____

RESEARCH GUIDE

Prof. Mrs. Vijayarani Prince, _____
M.Sc (N), M.A., M.A., M.Phil (N).
Principal,
Bishop's College of Nursing,
Dharapuram – 638656,
Tamilnadu

CLINICAL GUIDE

Prof. Mrs. Vijayarani Prince, _____
M.Sc (N), M.A., M.A., M.Phil (N)
Principal,
Bishop's College of Nursing,
Dharapuram – 638656,
Tamilnadu

MEDICAL GUIDE

Dr. Velavan D.M.R.T _____
Erode Cancer Centre
Velavan Nager
Perundurai Road
Erode – 638 009.

A DISSERTATION SUBMITTED TO THE TAMILNADU DR. MGR MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

2009 – 2011

A STUDY TO EVALUATE THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG

HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY IN SELECTED CANCER CENTERS AT ERODE.

APPROVED BY DISSERTATION COMMITTEE ON _____

RESEARCH GUIDE

Prof. Mrs. Vijayarani Prince, _____
M.Sc (N), M.A., M.A., M.Phil (N).
Principal,
Bishop's College of Nursing,
Dharapuram – 638656,
Tamilnadu.

CLINICAL GUIDE

Prof. Mrs. Vijayarani Prince, _____
M.Sc (N), M.A., M.A., M.Phil (N)
Principal,
Bishop's College of Nursing,
Dharapuram – 638656,
Tamilnadu

MEDICAL GUIDE

Dr. Sudhakar D.M.R.T., _____
HCG Cancer Center,
Perundurai Road,
Erode – 638 009.

A DISSERTATION SUBMITTED TO THE TAMILNADU DR. MGR MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

2009 – 2011

A STUDY TO EVALUATE THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG

HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY IN SELECTED CANCER CENTERS AT ERODE.

.

Certified Bonafide Project Work

Done By

MRS. D. BHARATHI,

M.Sc. Nursing II Year
Bishop's College of Nursing,
Dharapuram

_____ _____

Internal Examiner **External Examiner**

COLLEGE SEAL

A DISSERTATION SUBMITTED TO THE TAMILNADU DR. MGR MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

2009 – 2011

INDEX

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

APPENDICE- C

LIST OF EXPERTS FOR VALIDITY OF THE TOOL

1. **Mrs. Sheela Rosalena**
   Principal
   2/1, Kondapa Gardep
   Jeeva Nagalli
   Bangalore – 56005.

2. **Mrs. Malarvizhi**
   Vice Principal
   Collegeof Nursing
   PIMS
   Pondicherry .

3. **Mrs. Shobana**
   Asso. Professor,
   Annai JKK College of Nursing
   Kumarapalaym
   Namakkal District – 638 183.

4. **Mr. Ananth**
   Reader
   Mahalingam College of Nursing
   Sakthi Nagar,
   Bhavani.

5. **Dr. Velavan D.M.R.T**
   Erode Cancer Centre
   Velavan Nager
   Perundurai Road
   Erode – 638 009**.**

ABSTRACT

Oral mucositis is the painful inflammation and ulceration of the oral mucosa, usually as an adverse effect of radiation therapy. It is a major health problem and it can cause life style changes and there by it alters the quality of life of the patients with head and neck cancer under going radiation therapy. As a complementary alternative therapy apitherapy is given to the patients to improve the anatomical and functional abilities, there by improving the quality of the life of the head and neck cancer patients under going radiation therapy.

So the present study was done to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy in Erode Cancer Center and Human Care Global (HCG) Cancer Center at Erode.

The research design used for this study was quasi experimental design Non equivalent control group post test only design. Conceptual frame work adopted in the present study was modified Wiedenbach's - helping art of clinical nursing theory (1969). The sample size was 60 head and neck cancer patients undergoing radiation therapy among 60 head and neck cancer patients 30 for experimental group and 30 for control group. The samples were selected by purposive sampling method. In experimental group before 15 minutes of radiation therapy, 20ml of pure honey (apitherapy) was orally given to the patients to swish 20 ml of honey for 5 minutes then swallow it, again after 15 minutes of radiation therapy 20ml of pure honey (apitherapy) was orally given to the patients, ask the patient to swish 20 ml of honey for

5 minutes then swallow it, and advised the patient to repeat the same in their homes after six hours of radiation therapy. Apitherapy given daily from first day of 2nd phase of radiation therapy to last day of 3rd phase of radiation therapy(on 36th day)[about 14 days]. Where as in control group patients were treated as per hospital schedule. The post test done by using WCCNR oral mucositis scale was used to assess the anatomical alterations and observational checklist was used to assess the functional abilities after apitherapy among head and neck cancer patients undergoing radiation therapy.

The present study revealed that the post test mean score of experimental group was 4(SD ± 1.74) and the control group mean score was 9(SD ±3.01). The "t" value is 7.93 is greater than the table value (1.96) which is significant at 0.05 level which showed that there is a significant difference between the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy in experimental group and control group.

. The study revealed that apitherapy technique was highly effective in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy. Thus apitherapy technique played an important role in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy

ACKNOWLEDGEMENT

I am whole heartedly grateful to the Almighty God who strengthened, accompanied and blessed me throughout the study.

I extent my heartfelt thanks and gratitude to the management of Bishop's college of nursing for providing an opportunity to undergo to uplift my professional life.

I express my heart full thanks to our beloved **Madam Prof. Vijayarani Prince M.Sc., (N)., M.A., M.A., M. Phil(N), Principal, Head of the Department of Medical Surgical Nursing, Bishop's College of Nursing** for her encouragement, expert suggestions and support which helped me to overcome the hardships encountered during the study.

I convey my immense sense of gratitude to our **Administrator Mr. Johnwesley, Bishop's College of Nursing, Dharapuram** given me an opportunity to study in this esteemed institution.

I express my sincere gratitude for the valuable guidance and directions and support given by **Mrs. Geetha, M.Sc.(N), Lecturer, Medical Surgical Nursing Department** throughout the study.

I take immense pleasure and gratitude to our class co-ordinator **Prof. Glory Suramanjari, M.Sc. (N)** for her guidance and valuable suggestions throughout my study.

I thank to all the experts who have contributed their suggestions by validating the tool.

I extend my sincere thanks to **Mr. Murali, M.SC M.Phil. (Stat)** who aided me for statistical analysis.

My special thanks to **DR. Valavan DM. RT Medical oncologist Erode Cancer Center and DR. Sudhakar DM. RT Medical oncologist HCG Cancer Center at Erode** for guiding and giving me permission to conduct this study.

I would like to exclusively thank all the participants of the study for their co-operation.

I extend my thanks to **Mr.Samuavel sarguna Thangam MA. B.ED (Tamil) and Mr. R. Srinivasan , M.A. M. Phil., M.Ed., (English)** for their valuable help in English and Tamil editing for this study.

I express my thanks to **Vijay Computer Center and Staff** for their co-operation and untiring help in computerizing the material throughout the study for making me to complete the study in time.

I extend my sincere thanks to all **Library Staff** for rendering their support and help through out my study

THE COST EFFECTIVENESS OF HONEY

The total amount of honey used for 30 patients for 14 days of interventions is 25 liters, 200 ml. The total cost for the amount of honey spent was Rs. 4,410.

APITHERAPY PROCEDURE

Apitherapy (20ml) of honey orally given to the patients before 15 minutes and after 15 minutes of radiation therapy, ask the patient to swish 20 ml of honey for 5 minutes then swallow it and advise the patients to repeat the same in their homes after 6 hours of radiation treatment.

CHAPTER - I
INTRODUCTION

BACKGROUND OF THE STUDY :

"The concept of perfect positive health cannot become a reality because man will never be so perfectly adopted to his environment that his life will not involve struggles, failures and sufferings ".

Dubos., S. (2004)

Positive health will therefore, always remain mirages, because everything in our life is subject to change. Health in this context has been described as a potentiality-the ability of an individual to modify himself or itself continually in the face of changing conditions of life.

Park., K. (2007)

Decades before, Hippocrates said that cancer as a disease has existed all alones with man, susruta who is the father of surgery explained that cancer as a tumor which would ulcerate and would not cure and show its seeds in other parts of the body. Twenty-five centuries ago, cancer was called as Karakinos because the swollen blood vessels going and corning from the tumor mass.

Jaggi., O.P. (2006)

Cancer is one of the chronic and life-threatening diseases. It is a major barrier to socio economic development in the country because it is one of the causes of death of people. The World Health Organization predicts that in the year 2563 B.E, the amount of deaths will increase to 11 million people with 7 million of them come from developing countries.

Siriraj Cancer Center, (2004)

Head and neck cancer accounts for 20% of all malignancies and it was found in males more than in females. The peak is reached in the interval of ages from 40 to 70 years. Out of 10 types of cancer head and neck cancer is ranking the fifth most common cancer in men and the ninth in women.

National Cancer Institute, (2005)

The goal of cancer treatment to cure, control and palliation are achieved through the use of four treatment modalities include surgery, radiation therapy, chemo therapy and biologic therapy. Among these, surgery and radiation therapy have remained the most commonly used treatment modalities.

Lewis., S. (2004)

The major treatment for head and neck cancer primarily involves the three modalities: surgery, radiation therapy and chemotherapy, administered alone or in combination. The choice of modality depends primarily on site of lesions, tumor stages, opinions of physician and patient's factors. Radiation therapy and surgery are the main treatment modalities for head and neck cancer because most of them are squamous cell carcinoma that is sensitive to radiation, especially in the early–stage diseases.

Langendijk., J. (2005)

Radiation therapy is a therapeutic use of ionized radiation of the treatment of malignancies. Radiation is the emission and distribution of energy through space or a material medium. The energy produced by radiation, when absorbed into tissues, produces ionizing and excitation and breaks the chemical bonds in DNA, which leads to biological effect. Loss of proliferate capacity results in cellular death at the time of

division. Therefore cancer cells are more likely to be permanently damaged by cumulative doses of radiation.

Lewis .S. (2004)

Radiation therapy alone is the most common treatment for certain types of head and neck cancers, such as cancer of the nasopharynx, oralcavity, larynx and oropharynx. Radiation therapy is more likely to preserve structure function in the head and neck cancer when compared with surgical resection of the tumor. Despite the fact that it is an effective treatment, complication from radiation should be taken into consideration.

Jemal., (2006)

Radiation therapy of the head and neck region needs to pass the mucous membranes of the oral cavity that are highly sensitive to the radiation field. Therefore, this treatment modality leads to both acute and late complications after completion. Acute complications occurred in the short time after start receiving radiation such as oral mucositis, erythema and desquamation of the skin. Late complications are developing gradually over several months or years. It is the results of chronic injury to vasculature, salivary glands, mucosa such as xerostomia and dental decay. These symptoms may need to be treated repeatedly for recovering of the functions or maintain the functions if such function could not be recovered.

Narkwong., L. (2000)

Oral complication after radiation therapy for head and neck cancer can occur in almost all patients. These include oral mucositis, xerostoma, oral discomfort, pain, taste changes, dental carries, trismus, gingivitis, dysphasia and dysphonia.

Trotti., E.(2000)

There are a number of factors determining the severity of oral complications related to radiation therapy of head and neck cancer. Radiation factors include the total dose of radiation delivered, the treatment field and pathway of radiation beams, the dose per fraction and number of fractions per day, the volume of tissue treated, and the duration of the treatment course.

Louis., S. (2004)

Frank., **SJ et al** (**2004**), reported that during the past decade, improvements in treatment planning tools, computer and imaging technologies, and new therapeutic modalities have allowed radiation to be delivered in a conformal fashion while minimizing treatment toxicity. In the past few years, new 3- dimensional close-calculation algorithms finally, modern linear accelerators allow for modulation of the close intensity of the radiation beam, which may lead to decreased side effects while ensuring that the volumes at high risk relieve the prescribed dose. Radiation therapy can be delivered safely and effectively to patients with breast cancer.

Complementary alternative medicine has grown dramatically over the past several years. According to survey results 80% of patients repeated using some type of complementary alternative medicine, in that 50 % took herbal products and 30 % used relaxation techniques.

American Cancer Society, (2007)

Apitherapy is a type of complementary and alternative therapy which helps to reduce the degree of oral mucositis as a complication of radiation therapy. Apitherapy or bee therapy, is the product of the common honey bee for therapeutic purpose which involves the medicinal use of bee stings the venom and it has a strong anti

inflammatory and pain relieve effect, soften scar tissue and to boost the body's immune system. Thus it reduces the symptoms of oral mucositis.

The American Apitherapy Society (2008)

The contents of honey includes fructose(38.2%), glucose(31.3%), sucrose(1.3%),maltose(7.1%),water(17.2%),Highersugar(1.5%),ash(0.2%) and Other/undetermined(3.2%)

The honey act as a antimicrobial, antibacterial, antioxidant, broad spectrum of bacterial and fungal species, sedatives and honey strengthens the white blood corpuscles to fight bacteria and viral diseases.

The honey can be used as instant energizer in nature, it act as a traditional medicine which helps to reduce the swelling, ulcer, soothe the raw tissue, it helps to minizing disfiguring scar, providing energy to the body which restores the damaged skin and gives soft and give young looks.

http://www.ayurhelp.com (2010)

NEED FOR THE STUDY

Cancer is the leading cause of death around the world. According to WHO, which estimated that 84 million people will die of cancer between 2005 and 2015 without intervention. Low income and medium income countries are harder hit by cancer than the high resource countries. It is essential to address the world's growing cancer burden and to work on effective control measures.

WHO (2007)

Oral and pharyngeal cancer is the sixth most common malignancy reported worldwide and one with high mortality ratio

among all malignancies. The global number ofnew cases were estimated as 405,318, about two–thirds of them arising in developing countries. Highest rates are reported in south Asia countries such as India and Srilanka. In the USA alone, 30, 000 Americans are diagnosed with oral or pharyngeal cancer each year. About 90 percent of head and neck cancers are of the squamous cell variety.

Hamilton., N. (2010)

Cancer of the head and neck accounts for approximately 5% of all malignancies with over 40,000 new cases and 12,000 deaths per year in united states.

Vokes., E. (2003)

Globally the burden of new cancer cases in 2000 was estimated to be around 10 million with more than half of these cases originating from the developing world population. Although estimates vary it is estimated that by the year 2020 there will be almost 20 million new cases. From the population census data for India in 1991, 609,000 new cancer cases were estimated age standardized rates per 100,000 were 96.4 for males and 88.2 for females. The most common cancers found in males were cancers of the lung, pharynx, esophagus, tongue and stomach. While among females cancer of the cervix, breast, ovary, esophagus and mouth were common.

Bobba., R. (2003)

France is particularly concerned by head and neck cancers with 16,005 new cases and 5, 406 related deaths in year, in addition to tobacco and alcohol. Human papillomavirus (HPV) has been reported as a risk factor for head and neck cancers. In 2007, there were 36,268 patients hospitalized for head and neck cancers, of whom 81% were

men, corresponding to 60, 200 hospital stays and 2, 87, 846 sessions of chemo or radio therapy. Oro pharynx cancer was the most frequent (28%of patients) followed by oral cavity cancer (25% of patients). The peak of frequency was observed in the 55-59 years age group.

Guily., J. et'al (2010)

In Europe, head and neck cancer accounted for approximately 1, 43,000 new cancers in 2007 and were responsible of more than 68,000 deaths. In Europe tumors usually arise from the oral cavity, Oro pharynx or larynx where as Naso pharyngeal cancer is more common in the Mediterranean countries and in the Fast East countries

Guily., J. et'al (2010)

Head and neck cancer in Thailand accounts for 20% of all malignancies and it was found in males more than in females. The peak is reached in the interval of ages from40 to 70 years. Out of the10 types of cancer head and neck cancer is ranking the fifth most common cancer in men and ninth in women.

Kuthasema., P. (2008)

Head and neck cancers are common in several regions of the world where tobacco use and alcohol consumption is high. The age standardized incidence rate of head and neck cancer in males exceeds 30 per 100,000 regions of France, Hong Kong, the Indian sub-continent. Central and Eastern Europe, Spain, Italy, Brazil and among US blacks. The high rates > 10 per 100,000 in females are found in the Indian sub continent, Hong Kong, Philipplines. The highest incidence rate reported males in63.58% (France, Bas-Rhin) and in females 15.9% (India, Madras)

Sankaranarayanan., R. (1998)

One of the major reasons for the high incidence of oral cancer is the continued use of tobacco. It is estimated that around 40% of the men and 15% of the women use tobacco on a regular basis. However, in certain areas of the country regular use increases to over 85% in men and 65% in women. Women in Bangalore have one of the highest rates of cancer of the esophagus in the world- around eight per 100,000. While the men in Bhopal have the highest rate of cancer of the tongue in the world almost nine per 100,000. Tobacco related cancers account for about 52% of all cancers in males and 25% of all cancers in females.

Khan., Y. (2003)

Lung cancer is the most common cancer among men in India with approximately 33,000 new cases every year. In India squamous cell carcinoma is the commonest variety as compared to the adeno carcinoma in the west and the disease tends to occur early in India 51-60 years. Almost 90% of patients coming forward with lung cancers are smokers with the male to female ratio of approximately 10: 1

Pathak., A.K et'al (2003)

WHO (2007) reported that in India around 7.8 lakhs new cases of head and neck cancers are diagnosed every year. The head and neck cancer has become the 6th most common cause of human illness in India.

The incidence rates in some districts in India rank at the top of the global cancer charts, women in Delhi show the highest incidence of gall bladder cancer 10/1,00,000 kohima in Nagaland has a high incidence of cancer of nasopharynx, and 19/1,00,000 wardla in Maharashtra has a high incidence rate of mouth cancer in the world.

In Mumbai about 8,00,000 people are diagnosed with head and neck across the country each year. Tobacco related cancer accounting for at least 30% of all cancer.

Purvish., P. (2002)

In Delhi tobacco related lung cancer was the most common cancer (32.1%) followed by cancer of larynx 18.8%) and urinary bladder (5.6%). In females, cancer of the esophagus (29.9%) was the leading site associated with tobacco related cancer followed by lung (26.5%) and mouth (15.9%)

Raina V. (2007)

In Bangalore the total cancer cases are likely to go up from 9,79,786 cases in the year 2010 to 1,148,757 cases in the year 2020. The tobacco related cancers for males are estimated to go up from 1,90,244 in the year 2010 to 2,25,241 in the year 2020.

Takiar., R. (2010)

In Bangalore the number of cancer cases related to digestive system, for both males and females are estimated to be 1,07,030 and 86,606 respectively, for head and neck cancers the estimates are 1,22,643 and 53,148 cases respectively and for the lymphoid and hematopoietic system (LHS) 62,648 for males and 41,591 for females for the year of 2010.

Takiar., R. (2010)

In Dindigul District during the period of 1996-1998, 783 invasive cancers were registered, yielding an all-cancer crude incidence rate of 56.8/100,000 males and 88.5/100,000 females. The corresponding age standardized incidence rates(ASR) were 83.3 and 122.3 respectively. In males mouth cancer was the most frequent recorded malignancy

followed by tongue cancer(ASR 8.6), hypopharynx (ASR 7.8),esophagus (ASR 7.8) and larynx (ASR 7.8). Thus head and neck cancers accounted for half of the male cases. In females, cervical cancer (ASR 65.4) accounted for half of the cancers followed by breast (ASR 14.2) and mouth (ASR 10.2)

Rajkumar., R. et al (2009)

Biswal., et 'al (2003) did a study on topical application of honey in the management of radiation mucositis. The aim of the study was to evaluate the effect of pure honey on radiation induced mucositis. 40 patients diagnosed with head and neck cancer requiring radiation to the oropharyngeal mucosal area were divided into two groups to receive either radiation alone or radiation plus topical application of pure natural honey. Patients were treated using a 6 mv linear accelerator at a dose rate of 2 Gray per day five times a week up to a dose of 60–70 Gray. In this study arm, patients were advised to take 20 ml of pure honey 15 min before, 15 min after and 6 h post radiation therapy. Patients were evaluated every week for the development of radiation mucositis using the radiation therapy oncology group (RTOG) grading system. The main result of the study was there was significant reduction of symptomatic grade ¾ mucositis among honey–treated patients compared to controls. i e 20% versus 75% (p 0.00058). The compliance of honey treated group of patients was better than controls. As a conclusion topical application of natural honey is a simple and cost- effective treatment in radiation mucositis.

Apitherapy News (2008) the aim of the study is to evaluate the effect of pure natural honey on radiation induced mucositis. In this randomized single blind (examiner blind) clinical trial 40 patients with head and neck cancer requiring radiation to the oropharyngeal mucosa

were randomly assigned to two groups. Twenty patients assigned to the study group received honey, while both the study and control groups received standard head and neck radiation therapy based on a standard protocol. In the study group patients were instructed to take 20 ml of honey 15 minutes before radiation therapy, then again at the interval of 15 minutes and six hours after radiation. In control group patients were instructed to rinse with 20 ml of saline before and after radiation. Patients were evaluated weekly for progression of mucositis using the oral mucositis assessing scale (OMAS). Result shows a significant reduction in mucositis among honey received patients compared with controls (p = o.ooo) occurred. As a conclusion within the limits of this study the results showed the application of natural honey is effective I managing radiation induced mucositis.

Ahmad Zakaria., et al (2003) did a study on honey treatment for prevention of oral mucositis and gingivitis. Thus 20 – 40% of all cancer patients receiving intensive chemotherapy suffer from mucositis, the number climbs to 80% when chemotherapy and radiation are combined, and staggers even higher in patients receiving treatment for cancer in the head and neck area. The Biswal et' al investigated the use of honey in 40 adult patients with head and neck cancer. Patients consumed 20 ml (one and one- third teaspoon) of pure honey 15 minutes before, 15 minutes after and 6 hr post–treatment. There was significant reduction in the symptomatic grade three-four mucositis among honey treated patients compared with controls i, e 20% versus 75% ($p < 0.001$). In result the compliance of the honey treated group of patients was better than control. A total of 55% patients treated with topical honey showed no change or a positive gain in body weight compared with a positive gain in body weight compared with only 25% in the control arm(P =

0.05). As a conclusion honey has potential for the treatment of periodontal diseases, mouth ulcers and other problems of oral health and a trial has demonstrated a statistically significant difference between chewing gelled honey and chewing gum in decreasing the number of bleeding sites on gums with gingivitis.

Physically the oral mucositis can cause oral tissue damage and mucositis pain can be a significant problem for patients undergoing Cancer therapy. The frequency and severity of those problems can vary significantly with the type of therapy and from patient to patient. While oral complication primarily are associated with discomfort and interference with oral function. The frequency for these problems can range from a low of 2% of patients receiving adjuvant chemotherapy to a high of essential 100% of patients receiving radiation to the oral cavity, when doses exceed a total of 5000 cGray. The most notable complication include mucosal inflammation and ulceration, hemorrhage and xerostoma.

- The treatment of oral mucositis include general oral care protocols, interventions to reduce the mucosal toxicity of chemotherapy drugs, mouth wash with mixed action, immunomodulatory agents, topical anaesthetics((e.g viscous lidocaine, benzocaine sprays/gels, dyclonine rinses, diphenhydraminr solutions), Antiseptics, antibacterial, antifungal and antiviral agents, Mucosal barriers and coating agents(e.g antacid solutions, kaolin solutions), Mucosal cell stimulants (e.g hydroxypropyl cellulose), Analgesics(opiates are typically used.

The investigator has observed during her posting oncology ward that the head and neck cancer patients suffered with severe oral mucositis as adverse effects of radiation therapy and had problem in feeding.

The investigator felt that there is a need to do some intervention to reduce the oral mucositis in patients receiving radiation therapy to promote comfort and to improve their nutritional status. After reviewing related literatures the investigator came to know the Apitherapy has good effect in reducing oral mucositis in patients receiving radiation therapy. So the researcher planned to conduct a study by using Apitherapy in reducing the oral mucositis among the cancer patients undergoing radiation therapy.

STATEMENT OF THE PROBLEM :

A study to evaluate the effectiveness of Apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy in Selected cancer centers at Erode.

OBJECTIVES:

1. To assess the post test degree of oral mucositis in experimental group and control group.
2. To compare the effectiveness of Apitherapy in reducing oral mucositis between experimental group and control group.
3. To find the association between degree of oral mucositis after Apitherapy among head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental

HYPOTHESES:

H_1 : There is a significant reduction in the degree of oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy between experimental group and control group

H_2 : There will be a significant association between degree of oral mucositis after apitherapy among head and neck cancer patients under going radiation therapy with their selected Demographic variables in experimental group.

OPERATIONAL DEFINITION

EFFECTIVENESS:

Producing an intended result.

Soanes., C.(2001)

In this study it refers to determine the extent to which the apitherapy has brought about the significant difference in reducing degree of oral mucositis between experimental group and control group which is measured in terms of statistical measurement.

APITHERAPY

Apitherapy or bee therapy, is the products of the common honey bee for therapeutic purposes, which involves the medicinal use of bee stings the venom to reduce the inflammation and boost the body's immune system. These products are said to have medicinal effects and effective against a wide range of ailments, from arthritis and chronic pain to multiple sclerosis and cancer.

The American Apitherapy Society (2008)

In this study it refers to oral administration of 20 ml of pure honey (apitherapy) to the head and neck cancer patients before and after 15 minutes of radiation therapy. Ask the patient to swish 20ml of honey for 5 minutes then swallow it, and advised the patient to repeat the same in their homes after 6 hours of radiation therapy. Apitherapy was given daily from first day of 2nd phase radiation therapy (0n 23rd day) and continued till the end of the 3rd phase (upto 36day) (for 14 days)

ORAL MUCOSITIS:

Oral mucositis is an inflammation and ulceration of oral mucosa usually an adverse effect of radiation to head and neck oncology patients which is characterized by atrophy of squamous epithelial tissue, vascular damage, inflammatory infiltrates at the basement region, ulceration, fibrous (inflammatory pseudo membranous) exudates, pain and dysphasia and alteration in the taste and salivary flow

Jaggi., O.P (2006).

In this study it refers to head and neck cancer patient undergoing 2nd phase of radiation therapy with oral mucositis symptoms which includes inflammatory lesions, vascular changes, exudates, ulceration, pain, dysphasia, dryness, swelling, bad odor and alternation in taste and salivary flow.

The assessment of oral mucositis among head and neck cancer patients was done by using Western Consortium for Cancer Nursing Research (WCCNR) Scale and observational check list and its scores

HEAD AND NECK CANCER

Head and Neck cancer originating from the upper aero digestive tract, including nasal cavity and paranasal sinus, nasopharynx, oral cavity, oropharynx, hypopharynx, esophagus, larynx, salivary gland, thyroid gland orbit and ocular structure. Most head and neckcancers begin in the cells that line the mucosal surface in the head and neck area. They are often referred to as squamous cell carcinomas.

Hass, et al., (2007)

In this study it refers to head and neck cancer patients undergoing radiation therapy including nasal cavity, paranasal sinus, naso pharynx including oral cavity, tongue, oropharynx, hypopharynx. Esophagus, larynx, salivary gland and brain cancer.

PATIENT:

A person who is ill or undergoing treatment for a health care problem.

"In this study it refers to head and neck cancer patients undergoing 2nd phase of radiation therapy"(from 23rd day to 36th day) in out patient department.

RADIATION THERAPY:

Radiation therapy is the emission and distribution of energy through space or material medium. The energy produced by radiation, when absorbed into tissue, produces ionizing and excitation. This local energy is sufficient to break chemical bonds in DNA, which leads to biological effect.

Lewis. S. (2004)

In this study it refers to radiation conventionally given in daily fractions of 1.8Gray to 2.0 Gray, upto total doses of 66 Gray to 70 Gray over 6 to 7 weeks, which can be given in three fractions (phases) for head and neck cancer patients undergoing radiation therapy in out patient department

ASSUMPTIONS:

- Head and neck cancer patients undergoing radiation therapy are prone to develop oral mucositis.
- Apitherapy may reduce the oral mucositis among head and neck cancer patients undergoing radiation therapy.
- Nurses have an important role in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy.

DELIMITATION:

The study is delimited to

- Head and neck cancer patients undergoing 2nd phase of radiation therapy.
- The sample size for the study is limited to 60.
- The data collection period is limited to 5 weeks.

PROJECTED OUTCOME:

Apitherapy is given to the head and neck cancer patients undergoing radiation therapy to reduce the inflammation , pain, soften the scar tissue and to boost the body's immune system. Thus the degree of oral mucositis is reduced and promotes comfort and thereby improves the quality of life.

(ii) CONCEPTUAL FRAMEWORK

Conceptual framework helps to express abstract ideas in a more reality understandable or precise form of the original conceptualization. The conceptual framework for this study was direction from wieden bach's helping art of clinical nursing theory (1969).

According to Ernestine wiedenbach's nursing is nurturing and caring for someone in a motherly fashion. Nursing is a helping service that is rendered with compassion, skill and understanding to those in need for care, counsel and confidence in the area of health. The practice of nursing comprises a wide variety of services each directed toward the attainment of one of its three components.

Step I	:	Identification of a need for help.
Step II	:	Ministering the help needed .
Step III	:	Validation that the need for help was met.

Central purpose:

According to the theorist the nurse's central purpose defines the quality of health she desires to effect or sustain in her patient and specifies what she recognizes to be her special responsibility in caring for the patient. In this study the central purpose is to reduce the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy

STEP I- IDENTIFICATION OF A NEED FOR HELP:

According to the theorist within the identification component there are four distinct steps. First, the nurse observes the patient, looking for an inconsistency between the expected behaviour of the patient and the apparent behaviour. Second, attempts to clarify

what the inconsistency means. Third, determines the cause of the inconsistency. Finally, validates with the patient that her help is needed.

In this study the head and neck cancer patients undergoing 2nd phase of radiation therapy are selected for experimental group and control group. The general information which comprises assessment of demographic variables for both experimental and control group such as age, sex, education, occupation, , marital status, family monthly income, area of residence, religion, diagnosis, duration of illness and duration of treatment.

STEP II: MINISTERING THE HELP NEEDED

According to the theorist in ministering to the patient the nurse may give advice or information, make a referral, apply a comfort measures or carry out a therapeutic procedures. The nurse will need to identify the cause and if necessary make an adjustment in the plan of action.

Ministering of help needed it has two component.

- Prescription
- Realities

- **Prescription:**

According to the theorist a prescription is directive to activity. It specifies both the nature of the action that will most likely lead to fulfillment of the nurse's central purpose and the thinking process that determines it.

In this study Prescription apitherapy is the plan of care to achieve the purpose. This includes in experimental group oral administration of 20 ml of pure honey group before and after 15 minutes radiation

treatment advise the patient to swish it for 5 minutes then swallow it, and advise the patient to repeat the same for in their homes after 6 hours of post radiation for 14 days (from 23rd day to 36th day).

Realities

According to the theorist the realities of the situation in which the nurse is to provide nursing care. Realities consist of all factors -physical, physiological, emotional and spiritual that are at play in a situation in which nursing actions occur at any given moment. Wiedenbach's defines the five realities as the agent, the recipient, the goal, the means and the framework.

- **Agent**

According to the theorist, the agent is the practicing nurse or her delegate is characterized by personal attribute capacities, capabilities and most importantly commitment and competence in nursing**.** In this study the investigator is the agent.

- **Recipient**

According to the theorist the recipient is the patient, is characterized by the personal attributes, problem, capabilities, aspirations and most important the ability to cope with the concerns or problems being experienced. In this study the recipients are head and neck cancer patients undergoing 2nd phase of radiation therapy..

- **Goal**

According to the theorist the goal is the desired outcome the nurse wishes to achieve. The goal is the end result to be attained by nursing action**.** In this study it refers to reduce the degree of oral

mucositis among head and neck cancer patients undergoing radiation therapy.

- **Means**

According to the theorist the means comprise the activities and devices through which the practitioner is enabled to attain her goal. The means include skills, techniques, procedures and devices that may be used to facilitate nursing practice. In this study it refers to oral administration of apitherapy for 14 days in experimental group.

- **Framework:**

According to the theorist the framework is consists of the human environmental, professional and organizational facilities that not only make up the context within which nursing is practiced but also constitute is currently existing limits .In this study it refers out patient department of Erode Cancer Centre and Human Care Global (HCG) Cancer Center at Erode.

STEP III : VALIDATION THAT THE NEED FOR HELP WAS MET

According to the theorist the third component is validation. After help has been ministered the nurse validates that the actions were indeed helpful. Evidence must come from the patient that the purpose of the nursing actions has been fulfilled.

In this study, validating the need for help was met by means of post assessment for both experimental and control group with the WCCNR Scale and by observational check list to assess the degree of oral mucositis on the 14th day.

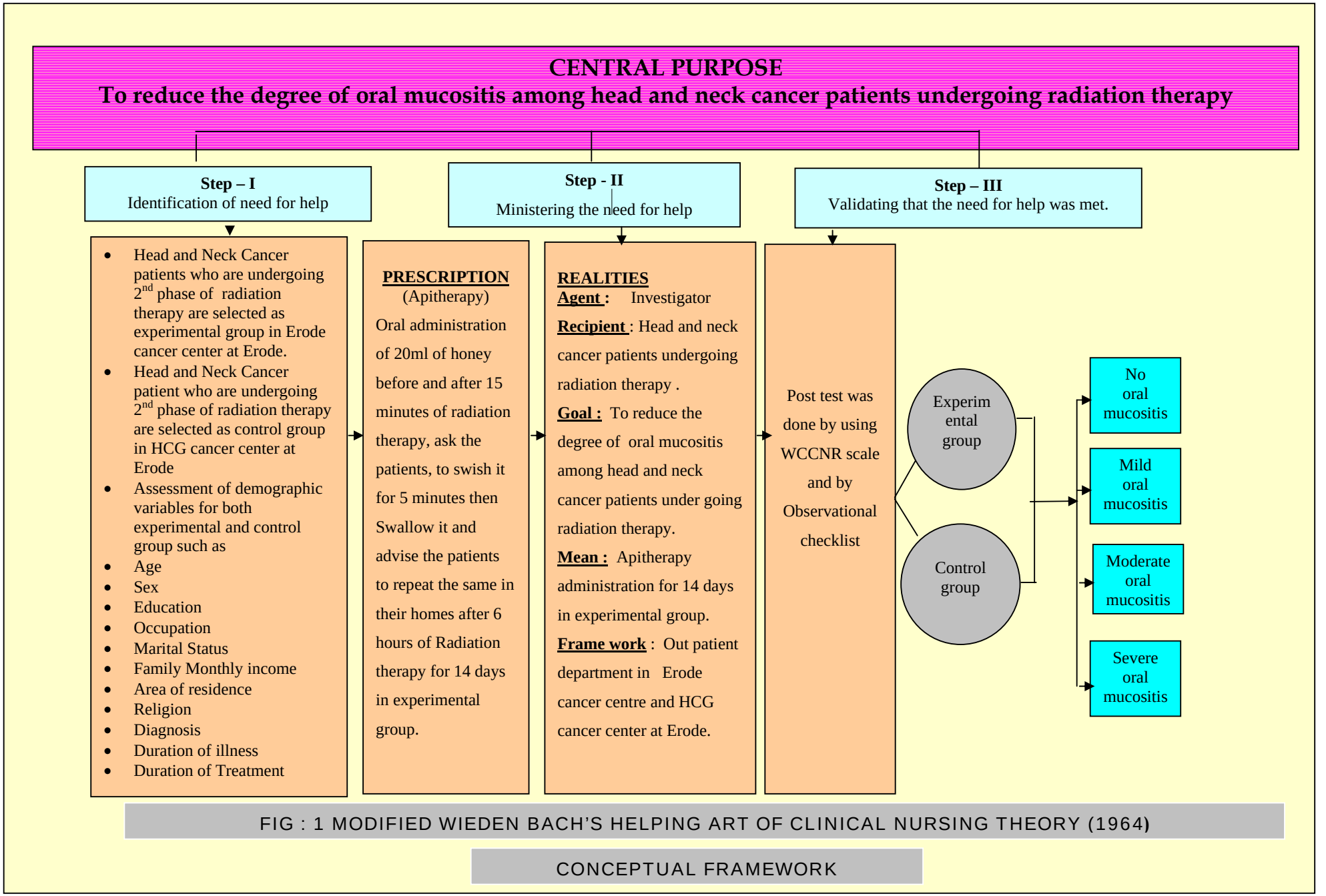

FIG : 1 MODIFIED WIEDEN BACH'S HELPING ART OF CLINICAL NURSING THEORY (1964)

CONCEPTUAL FRAMEWORK

CHAPTER –II

REVIEW OF LITERATURE

The literature review involves the systematic identification, location, scrutiny and summary of written materials that contain information of a research problem (Polit and Hungler 2004)

The literature gathered from through review is depicted under the following headings.

PART – I

A) Over view of Head and Neck cancer

B) Radiation therapy and its side effects

C) Oral mucositis

PART – II

A. Studies related to radiation induced oral mucositis among head and neck cancer patients undergoing radiation therapy

B. Studies related to complementary and alternative therapy in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy

C. Studies related to Apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy

PART – I

A) Over view of Head and Neck cancer

INTRODUCTION

The word neoplasm derived from the Greek word neos, means "new", and plasis, means "molding". It is derived as an abnormal mass of tissue that serves no useful purpose and may harm the host organism. A neoplasm can be either benign or malignant. A benign neoplasm is usually a harmless growth that does not spread or invade other tissues. A benign tumor does occupy the space. A malignant neoplasm's a harmful mass, capable of invasion of other tissues and metastasis ("spread") to distant organs.

Basavanthappa., B.T., (2003)

DEFINITION

Head and Neck cancer originating from the upper aero digestive tract, including nasal cavity and paranasal sinus, nasopharynx, oral cavity, oropharynx, hypopharynx, esophagus, larynx, salivary gland, thyroid gland orbit and ocular structure. Most head and neck cancers begin in the cells that line the mucosal surface in the head and neck area. They are often referred to as squamous cell carcinomas.

Hass, et al., (2007)

Incidence

- An estimated 8300 new cases of oral and pharyngeal cancer are diagnosed each year in the united states.
- 2000 deaths occur each year due to head and neck cancer
- Most (90%) head and neck cancers occur in incidence 50 years or older after prolonged use of tobacco and alcohol
- Males are affected at a 2 to 5 times greater rate than women.

Lewis, et al., (2004)

CAUSES AND RISK FACTORS OF HEAD AND NECK CANCER

Several risk factors make a person more likely to develop head and neck cancer

- **TOBACCO**

It is refers to cigarette smoke and chewing tobacco, pipe smoke, and cigars. Smoking is a major factor to increase risk of cancer related to cancer of larynx or hypo pharynx 5 – 35 times of nonsmokers.

- **ALCOHOL CONSUMPTION**

Increase one's chance for laryngeal cancer approximately 2-5 times that of non drinkers, and in combination with tobacco use has been shown to have almost a multiplying effect on the risk.

- **VIRUS**

Human papillomavirus (HPV) infection is the possible cause of oral cavity carcinoma and oropharyngeal carcinoma. Epstein –Barr virus (EBV) is specially associated with nasopharyngeal carcinoma.

- **ENVIRONMENT IRRITANTS**

Exposure to inhaled drugs, toxic dry cleaning solvents or pain fumes, wood dust and asbestos are considered risk factors for cancer of larynx, paranasal sinus and nasal cavity and nasopharynx.

- **DIET**

It was believed that high dietary intake of salty cured fish and meat is high risk for nasopharyngeal cancer

Basavanthappa, B.T., (2003)

CLASSIFICATION

Head and neck squamous cell carcinomas make up the vast majority of head and neck cancers, and arise from mucosal surfaces through this anatomic region. These incidence tumors of the nasal cavities, paranasal sinuses, oral cavity, nasopharyx, oropharynx, hypopharynx, larynx, trachea, cancer esophagus, salivary gland cancer and brain cancer.

Joyce M. Black., (2005)

- **ORAL CAVITY**

Squamous cell cancers are common in the oral cavity, including the inner lip, tongue, floor of mouth, gingival, and hard palate. It is strongly associated with tobacco use especially use of chewing tobacco (or) heavy alcohol use.

- **NASO PHARYNX**

It arises in the nasopharynx the regin in which the nasal cavities and the Eustachian tube connect with the upper part of the throat.

- **OROPHARYNX**

It begins in the oropharynx, the middle part of the throat that includes soft palate, the base of the tongue and the tonsils. Squamous cell cancers of the tonsils are more strongly associated with human papilloma virus infection than are cancers of other regions of the head and neck.

- **LARYNX**

Laryngeal cancer begins in the larynx or "voice box"cancer may occur on the vocal folds themselves("glottis"cancer) or on tissues above and below the true cords ("supra glottis and subglottic cancers respectively). Laryngeal cancer is strongly associated with tobacco smoking.

- **TRACHEA**

Cancer of the trachea is a rare malignancy which can be biologically similar in many ways to head and neck cancer, and is some times classified as such most tumors of the salivary glands differ from the common carcinoma of the head and neck which includes teratomas, adenocarcinoma, denoid cystic carcinomas and mucoepidemoid carcinomas.

Joyce M. Black., (2005)

- **CANCER OF ESOPHAGUS**

A malignant tumor of the esophagus. The risk of cancer of the esophagus is increased by long-term irritation of the esophagus, such as from smoking, heavy alcohol intake and Barrett esophagus. As the tumor occur the common symptoms includes difficulty in swallowing, feeling of fullness, pressure, difficulty in swallowing. As the grows larger and the pathway to the stomach becomes narrows, even liquids can be hard to swallow and swallowing may impaired.

- **SALIVARY GLAND CANCER**

Salivary gland cancer is a rare form of cancer that begins in any of the salivary glands in the mouth, neck or throat. The salivary gland cancer occur most commonly occurs in the parotid gland which is just in front of the ear.

- **TONGUE CANCER**

Tongue is malignant or squamous cell carcinoma of the tongue. Tongue cancer is divided in to anterior tongue and that the base or the tongue. The base of the tongue is the site of any one third of all tongue cancer, but these tumors to be for more advanced and aggressive that

these of the front of the tongue. The symptoms of the tongue may be odynophagia, otagia and mass in the neck

- **BRAIN CANCER**

The tumors in the brain can be malignant or benign, can occur at any age. Only malignant tumors are cancerous. Primary brain tumors cancer initially forms in the brain tissue. Secondary brain tumors cancers are cancers that have spread to the brain tissue, (metastasized) from elsewhere in the body. Secondary brain cancer is named for the organ or tissue in which the cancer begins, such as lung cancer with secondary metastasis.

Joyce M. Black., (2005)

CANCER STAGING

Staging describes the extent of cancer, especially whether the disease has spread from the original site to other parts of the body. Staging is important in cancer diagnosis because it assists the physician with determining the progression of a disease in order to choose an appropriate method of treatment and to accurately assess a prognosis

The TNM staging system is one of the most commonly used staging systems. It is based on the extent of the tumor (T) the extent of spread to the lymph nodes (N) and the presence of metastasis(M).Once the T, N and M are determined a "stage" of I, II,III or IV is assigned by the physician

Stage I	Cancers are small, localized and usually curable
Stage II and III	Cancers typically are locally advanced and have spread to local lymph nodes

Stage IV Cancers usually are metastasis (have spread to distant parts of the body) and generally are considered inoperable.

Haggood., (2001)

SIGNS AND SYMPTOMS:

- Enlarged lymphnode
- Numbness or paralysis of the facial muscle
- Mass in the neck
- Neck pain
- Bleeding from the mouth
- Bad breath
- Painless ulcer or sores in the mouth that do not heal
- White or red and dark patches in the mouth
- Earache
- Unusual bleeding and numbness in the mouth
- Lump in the lip, mouth or gums
- Enlarged lymph glands
- Slurring of speech
- Hoarse voice with persists for more than six weeks
- Sore throat with persists for more than six weeks
- Difficulty swallowing foods
- Changes in diet or weight loss

DIAGNOSTIC EVALUATION

- Indirect laryngoscope and nasopharyngoscope may be used to detect the tumor size.
- Cytology studies
- Chest x-ray

- Complete blood count
- Radio isotope scans
- CT scan and MRI may performed
- Position emission tomography (PET) may be used
- Needle biopsy
- Incisional biopsy performed with a scalpel or dermal punch is a common technique used for obtaining a tissue sample for making a diagnosis of cancer
- Excisional biopsy involves removal of the entire tumor. It is usually used for small tumors (smaller then 2cm)
- Histopathologic studies

Joyce M. Black., (2005)

TREATMENT OF HEAD AND NECK CANCER

The three main types of treatment of managing head and neck cancer surgery, radiation therapy and chemotherapy.

(i) surgery

Surgery is an important part of the treatment of head and neck cancers and aims to remove them completely, especially in patients with early stage head and neck cancers. The surgeon may remove the cancer and some of the healthy tissue around it, lymph nodes in the neck may also be removed if the doctor suspects that the cancer spread.

Vokes, E.,(2003)

(ii) Chemotherapy

It is the use of anti-cancer drugs to destroy cancer cells. They work by disrupting the growth of cancer cells which may be used before or after surgery or radiation therapy to make treatment that is

more effective. Some times chemotherapy given along with radiation therapy. It may also be given to people whose cancer has spread to other parts of the body or whose cancer has replace after radiation therapy.

Hoffman, E., (1998)

(iii) Radiation Therapy

It is the use of high energy x-rays and similar rays such as electrons to treat the disease. Patients with early stage head and neck cancers are treated with one modality or combination. Radiation therapy (RT) alone is the most common treatment for certain types of head and neck cancers, such as cancer of the nasopharynx, larynx and oropharynx

Vokes, E.,(2003)

(iv) INTENSITY MODULATED RADIO THERAPY (IMRT THERAPY)

It is the most common form of treatment. One of newer treatment is intensity–modulated radiotherapy or IMRT which is able to focus more precisely so that fewer healthy cells are destroyed than was the case with some of the older radiation therapies. IMRT reduces incidental damage to the many important structures of the throat and mouth that may not be involved. Radiation will generally cause the patient to feel sicker and weaker for several weeks following the treatment, but it is a very effective treatment in stopping the disease.

(v) Targeted Therapy

Molecular markers that have prognostic and treatment value are currently under investigation. Epidermal growth factor receptors

(EGFR) and human papilloma virus (HPV) are already being used in this manner and many new markers are currently under investigation. These markers will allow the development of new therapies and the idealization of existing treatment options to create personally tailored regimens for each patient.

(vi) NECK DISSECTION

Modified neck dissection is designed to preserve the spiral accessory nerve, the great auricular, and the and the sternocleidomastoid muscle. The jugular vein and submandibular gland also have been preserved. In addition, successful result can be achieved through less then complete lymph node removal, selectively remove only those lymph node level likely to be involved by metastasis. Modified neck dissection removes all five lymph node levels, preserving one or all of the spiral accessory nerve, jugular vein and sternocleidomastoid muscle.

Vokes, E.,(2003)

(vii) PHOTOSENSITIZERS AND INTERSTITIAL LASER THERAPY

Photosensitizing drugs that concentrate in cancer cells from the basis for photodynamic therapy, Activation of the drug with light results in cancer cell death . Laser photothermal ablation may be an alternative to surgery for the palliative treatment of head and neck cancer because of its tissue-sparing access, the possibility of repeated treatment and experimental evidence suggesting lower recurrence at tumor margins compared with surgery. The combination of interstitial laser therapy with regional chemotherapy agents that are cultivated by light of heat is under investigation as a combined therapeutic regimen.

(viii) IMMUNE THERAPY

Recruitment of immune cells and administration of stimulatory immune factors to arrangement treatment of cancer. Through the immune response have been advocated but have had little success to date in treating head and neck cancers. Nonspecific immune o adjustment systemic treatment with factors, such as levamisole or Bacillus Chalmette- Guerin (BCG) to targeted treatment with purified or recombinant factors, such as interferon or interleukin -2(12-2) have not improved either response rate or duration. Severe toxicities also are associated with the systematic use of these factors.

(ix) GENE THERAPY

Gene therapy involves delivery vehicles that can transfer therapeutic genes to target cells. Therapeutic genes may encode a product that induces a biologic response, such as activation of the immune system with transferred interleukin sequences. Head and neck cancers are known to have high levels of P 53 mutations. Normal functions of P 53 are cell growth regulation. Insertion of the P 53 gene into various tumor cell lines in vitro and into animal models in vivo has resulted in suppressed cell growth through cell cycle arrest and apoptosis. Head and neck cancers are accessible to injection therapy and are good candidates for trials of P 53 gene therapy.

Vokes, E.,(2003)

B) Radiation Therapy for head and Neck cancer

Radiatiopn therapy is the most commonly modality used for head and neck cancers, definitive treatment of them is conventionally given in daily fractions of 1-8 Gray to 2.0 Gray up to total doses of 66 Gray to

70 Gray over 6 to 7 weeks. It can be given as a three divided fractions like first phase, second phase and third phase.

Gorden,, A.,(2002)

MECHANISM OF RADIATION TO CANCER CELL

Radiation therapy may also be called radiotherapy, x-ray therapy, or irradiation. It uses ionizing radiation to kill cancer cells and shrink tumors. Radiation therapy injures or destroys cells in the target tissue by damaging their genetic, making it impossible for these cells to continue to grow and divide. Radiation damages both cancer cells and normal cells. Most normal cells can recover from the effect of radiation and function properly. The goal of radiation therapy is to damage as many cancer cells as possible, While limiting harm to nearby healthy tissue.

National cancer institute, (2004)

Radiation therapy may be used alone, instead of surgery. It can also be use after an operation, to destroy small areas of cancer that could not be removed by the surgery, or may also be given in combination with chemotherapy (chemo -radiotherapy).

RADIATION THERAPY METHODS

Radiation can be given in one of two ways.

External Beam Radiation Therapy is the most common form of radiation therapy. A beam of radiation is directed through the skin to the cancer and the immediate surrounding area in order to destroy the main tumor and any nearby cancer cells. A machine called a linear accelerator, or linac usually generates the radiation beam. It is capable of producing high energy x-rays and electrons, but gamma rays beams

from cobalt unit and lower energy x-rays. Types of equipment are cobat-60 machines and linear accelerators.

Internal radiation therapy also called brachytherapy, Interstitial radiation therapy, or implant therapy. It involves putting a radio active material directly into the cancer given by inserting radio active needles or wires into the cancer site, under a general anesthesia.

Basavanthappa., B.T. (2003)

SIDE EFFECTS OF RADIATION THERAPY

Side effects and potential complications of radiation therapy are often found and when they do occur, are typically limited to the areas that are receiving treatment with radiation. The radiation side effects experienced by the normal body tissue during and after radiation therapy can be loosely divided into acute and late effects.

1. ACUTE RADIATION SIDE EFFECTS

Constitute the acute reaction occurring during radiation and in the immediate weeks and months following treatment.

1.1) FATIGUE

The combination of nutritional factors, anemia, self. Care demands, and insomnia are likely play a role in fatigue development. Fatigue is insidious and accumulate over the course of treatment peaking 1 to 3 weeks after completion of treatment.

1.2) Skin Reaction

Patients being treated for head and neck cancers develop skin reaction beginning 3 to 4 weeks during treatment. It is a temporary

expected part of the treatment process and is experienced by nearly everyone treated with radiation

Hass., et 'al. (2007)

1.3) Oral mucositis

It is especially severe in patients receiving radiation to the head and neck because the majority of the oral and pharyngeal mucosa is directly in the path of the radiation beam. The severity of mucositis increases as the dose of radiation escalates. As radiation continues to total dose of 5 to 6 Gray the worst mucosal reaction occur.

National Cancer Institute. (2002)

1.4) Xerostoma

The subjective experience of dryness in the mouth, is a common and often irreversible effect of head and neck irradiation. Low radiation doses can cause noticeable changes. A radiation dose as little as Gray at approximately 1 week after starting can lead to xerostoma.

1.5) Taste change

Related to radiation therapy is first noticed during the second week of treatment. Taste alternations are believed to result from both the loss of saliva and the direct pathological effect of radiation of taste cells. Taste buds show signs of degeneration and atrophy at 1Gray and at 3 Gray the patient begins to notice a loss of taste.

Hass., et 'al.(2007)

1.6) Nutritional deficit

The structures of the head and neck, oral cavity, oropharynx and pharynx mucosa are often received directed from radiation therapy within the treatment fields. It was lead within a negatively affect ability's patients to eat, food intake and nutritional status

2. LATE RADIATION SIDE EFFCT

It is developing gradually over several months or years, side effects are usually temporary and resolve once the radiation is completed.

2.1) Xerostoma

Which begins during the acute phase of radiation therapy, continues throughout the remainder of patient's lives. The degree of dryness is variable, but leads to an increase risk of cavities and bone damage after radiation treatment.

2.2) Osteoradionecrosis(ORN) describes a condition of impaired healing and necrosis of the jawbone after radiation therapy. It can occur in 5% to 15% of patients receiving radiation therapy, and typically presents after a tooth extraction from the mandible.

2.3) Hypothyroidism is resulted from effects of radiation therapy on the thyroid gland itself, occurring in approximately 15% of patients treated for advanced head and neck cancer

2.4) Trimus

It is defined as the contraction of the muscles of mastication, restriction in ability to open the mouth. Radiation doses greater than 60 Gray directed to the temparomandibular joint

Hass., et 'al. (2007)

2.5) Dysphagia or difficulty swallowing after treatment for head and neck cancers, negatively affects patients quality of life. It is estimated that more than 25% of patients with nasopharyngeal carcinoma have significant dysphagia

From the review literature, the most common side effects anticipated with treatment to the head and neck area include fatigue, oral mucositis, osteoradionecrosis, dental problem, taste alterations and acute and chronic xerostomia.

C) ORAL MUCOSITIS

Oral mucositis is actually a widespread and possible serious consequence of high-dose chemotherapy and radiotherapy treatments frequently becoming evident as erythematic and aching ulcerative abrasions of the mouth and even the throat.

DEFINITION

Oral mucositis is the painful inflammation and ulceration of the oral mucosa, usually an adverse effect of radiation therapy.

INCIDENCE

- Patients treated for head and neck cancer
- Patients undergoing intensive high-dose chemotherapy
- Patients undergoing intensive high-dose chemotherapy For bone marrow transplantation

CAUSES

- Oral mucositis has been recognized as the extremely devastating consequence of anti cancer treatment by victims who went through it.
- Patient undertaking myelotoxic therapy for hematopoietic stem cell transplantation(HSCT)
- Increased hospitalization and feeding tube placement are also required more commonly for patients who receive radiation therapy and experience severe oral mucositis

PATHOPHYSIOLOGY

` Oral mucositis usually develops within seven to fourteen days after chemotherapy or radiation therapy is initiated. Mucositis secondary to radiation results from repeated tissue damage from multiple daily treatments. It begins to manifest at doses of 1000 to 2000 cGray (1 to 2 weeks of therapy) and is limited to the field of radiation. Initial signs may include mucosal whitening due to transient hyper-keratinization followed by erythema, or erythema may occur first. Ulceration then occur typically at doses over 3000 cGray. Following the end of radiation treatment, it requires three to six weeks for oral tissue to heal. In contrast, chemotherapy-related oral mucositis occurs on non-keratinized oral mucosa tissue only, and the most severe oral ulceration tends to occur when the patient reaches the nadir of their white blood cell count. Healing will occur within two to three weeks after chemotherapy is ended.

SIGNS AND SYMPTOMS OF ORAL MUCOSITIS

- Red, shiny, or swollen mouth and gums
- Blood in the mouth
- Sores in the mouth or on the gums or tongue
- Soreness or pain in the mouth or throat
- Difficulty swallowing or talking
- Feeling of dryness, mild burning, or pain when eating food
- Soft, whitish patches or pus in the mouth or on the tongue
- Increased mucus or thicker saliva in the mouth

DIAGNOSIS

- The diagnosis of grade 1 mucositis is based on the presence of asymptomatic mucosal erythema, evaluated on clinical ground,

and no treatment, it is common infection during head and neck radiotherapy and antineoplastic chemotherapy. In this stage patients needs antifungal treatment.

- Laboratory findings of candida smear
- Grade II mucositis is also diagnosed upon the clinical presentation
- Grade III & IV mucositis is diagnosed upon its clinical presentation of superficial ulcerations covered by pseudomembranes that are very painful to be rubbed off.
- Laboratory isolation of yeasts from smears, taken from the lesions to identify herpes simplex viruses.

SCALES USED FOR ORAL MUCOSITIS

There are numerous scales used to grade the severity of mucositis. The most commonly used scales are the World Health Organization(WHO) scale and the National Cancer Institute-Common Toxicity Criteria (NCI-CTC) scales. These scales employ a combination of objective scales in clinical trials.

Grade	0	1	2	3	4
WHO (World Health Organization)	None	Soreness, Erythema	Erythema, ulcers and patient can swallow solid food	Ulcers with extensive erythema and patient cannot swallow solid food	Mucositis to the extent that alimentation is not possible
RTOG (Radiation Therapy Oncology Group)	None	Erythema of the mucosa	Patchy reaction<1.5 cm, noncontiguous	Confluent reaction>.5cm, contiguous	Necrosis or deep ulceration, bleeding
WCCNR (Western Consortium Cancer Nursing Research)	Lesions : None Colour : pink Bleeding : None	Lesions:1-4 Colour: Slight Red Bleeding: N/A (N/A= Not Applicable)	Lesions:>4 Colour; Moderate Red Bleeding Spontaneous	Lesions: Coalescing Colour: Very Red Bleeding: Spontaneous	

TREATMENT

Many different treatments are used to prevent or treat oral mucositis.

- General oral care protocols
- Interventions to reduce the mucosal toxicity of chemotherapy drugs
- Mouth washes with mixed action (e.g 0.9% normal saline and/or sodium bicarbonate solutions)
- Immunomodulatory agents(Ig E, Ig M)
- Topical anaesthetics((e.g viscous lidocaine, benzocaine sprays/gels, dyclonine rinses, diphenhydraminr solutions)
- Antiseptics (Chlorexidine, dyclonine rinses)
- Antibacterial, antifungal and antiviral agents(betadine oral solutions, hydrogen peroxide diluted with water solutions, acyclovir, allopurinol mouth rinse may used)
- Mucosal barriers and coating agents(e.g antacid solutions, kaolin solutions)
- Mucosal cell stimulants(e.g hydroxypropyl cellulose)
- Analgesics(opiates, capsaicin preparations are typically used.)

GENERAL ORAL CARE PROTOCOLS

Use the following mouthwash 4 times a day to rinse

- 3% Hydrogen peroxide
- Fluoride toothpaste or solution
- Warm water
- Baking soda with salt solution
- Bland rinses (0.9% normal solution or sodium bicarbonate solutions)

INTERVENTIONS WHICH REDUCE THE MUCOSAL TOXICITY OF CHEMOTHERAPY DRUGS

It include allopurinol and cryotherapy.

Allopurinol mouthwashes 4 to 6 times per day have been evaluated as prophylaxis against mucositis resulting specifically from the action of 5-fluorouracil chemotherapy.

Cryotherapy or rapid cooling of the oral cavity using ice, causes local vasoconstriction and hence reduces blood flow to the oral mucosa . cryotherapy may reduce the amount of drug reaching the oral mucous membrane, and may therefore reduce mucositis caused by local cytotoxic activity of these drugs.

MOUTHWASHES WITH MIXED ACTIONS

Mouth washes with mixed action have been evaluated and include benzydamine hydrochloride, corticosteroids and chamomile. Benzydamine hydrochloride is a drug which has anti-inflammatory, pain relieving, antipyretic and antimicrobial activities, and has been used as a gargle or mouthwash to prevent and treat oral mucositis. It is a good evidence that benzydamine hydrochloride mouthwash is effective in improving the symptoms of radiation induced mucositis in patients with head and neck cancer.

ORAL HYGEINE

Oral care to remove potential sources of infection provide in conjunction with cancer therapy is necessary to prevent serious complications, including rampant decay and osteoradionecrosis with radiation therapy and potentially life-threatening infections and bleeding with chemotherapy. Several studies have shown a reduction in oral mucositis in patients who received oral care to remove sources of

infection before and during their cancer therapy. Many investigators feel oral care with cancer therapy is beneficial, but the effect on mucositis is yet to be proven.

INFECTION PREVENTION

It has been postulated that infection may play a role in the severity of cancer therapy oral mucositis, and this area has been investigated extensively. Two studies have shown that use of a topical antimicrobial lozenge containing polymyxin, tobramycin, and amphotericin B reduced oral mucositis with radiation therapy. Chlorhexidine oral rinses have been shown in several studies to reduce oral mucositis, particularly in patients receiving hematopoietic stem cell transplant (HSCT) and radiation

Hass., M. et al(2007)

GOOD NUTRITION

Food taken should be soft, non-spicy, pureed or in s liquid form only. Hard foods must be cooked until soft. Foods that burn or irritate the oral area must be kept away. Food products such as cooked cereal, apple sauce, mashed potatoes, filtered soups, gelatin, custard, eggs and puddings can be taken without any trouble to eat.

GOOD ORAL CARE

Regular check of mouth for swelling, pain, ulcers, or sores, redness, brushing one's teeth with gentle brushes twice or thrice a day. Cleaning out floss between the teeth and using alcohol-free wash for mouth. There is some intervention in complementary and alternative therapy in reducing degree of oral mucositis, so the researcher planned to do honey(apitherapy) as a complementary and alternative therapy in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy.

HONEY (APITHERAPY)

INTRODUCTION

Honey is one of nature's wonder. it is nectar gathered from the blossoms of many flowers by bees. It is then taken in to the beehive and changed by the worker bees. Worker bees remove the liquid from the nectar. The finished product is heavy syrup with 12 to 20 percent moisture and 80 to 85 percent sugar. It is a good source of quick energy for the human body.

DEFINITION

The definition of honey stipulates a pure product that does not allow for the addition of any other substance. This includes water or other sweeteners.

THE CONTENTS OF HONEY

- Sugar like fructose, glucose, sucrose, maltose, lactose and other disaccharides and trisaccharides
- Proteins, fats, vitamins, minerals, enzymes and amino acids
- Volatile aromatic substances
- Ashes and water etc

THE HONEY ANALYSIS

• Fructose	:	38.2%
• Glucose	:	31.3%
• Sucrose	:	1.3%
• Maltose	:	7.1%
• Water	:	17.2%
• Higher sugar	:	1.5%
• Ash	:	0.2%
• Other/undetermined	:	3.2%

NURTITIONAL VALUE PER 100g (3.5oZ)

• Energy	:	1,272 KJ (304 K cal)
• Carbohydrate	:	82.4 g
• Sugars	:	82.12 g
• Dietary fiber	:	0.2 g
• Fat	:	0 g
• Protein	:	0.3 g
• Water	:	17.10 g
• Riboflavin (vit.B2)	:	0.038 mg (3%)
• Niacin (vit.B3)	:	0.121 mg (1%)
• Pantothenic acid (B5)	:	0.068 mg (1%)
• Vitamin B6	:	0.024 mg (2%)
• Vitamin C	:	0.5 mg (1%)
• Calcium	:	6 mg (1%)
• Iron	:	0.42 mg (3%)
• Magnesium	:	2 mg (1%)
• Phosphorus	:	4 mg (1%)
• Potassium	:	52 mg (1%)
• Sodium	:	4 mg (0%)
• Zinc	:	0.22 mg (2%)

BENEFITS OF HONEY

- The most common use of honey as a microbial agent it as a dressing for wounds, burns and skin ulcers. This application has a long history in traditional medicine, additionally the use of honey reduces odors, reduces swelling, and reduces scarring, it also prevents the dressing from sticking to the healing wound.

- The honey has antibacterial properties has been established for over a century, but in many cultures it has been used as a medicine. It is now less established that honey inhibits a broad spectrum of bacterial and fungal species.
- Honey has powerful antimicrobial properties, which can soothe your raw tissue. Pour a teaspoon of honey into a large serving spoon and then top off the spoon with lemon juice. Swallow the concoction (without water) every few hours until symptoms clear up. Some people add a pinch of black or red pepper to increase blood circulation to the throat
- Honey is useful for the skin diseases. It can be applied externally for wounds, sores and burns. It is also believed to minizing disfiguring scar.
- Honey is useful in providing energy to the body.
- As it contains sugars which are quickly absorbed by the digestive system and converted in to energy. This can be used as instant energizer.
- As it is hygroscopic, it speeds up healing tissue and dries it up.
- Honey act as a sedative and it very useful in bed wetting disorders.
- Honey is very good antioxidant which restores the damaged skin and gives soft, young looks.
- Honey has antibacterial properties due to its acidic nature and enzymatically produced hydrogen peroxide.
- Constant use of honey strengthens the white blood corpuscles to fight bacteria and viral diseases.

PRECAUTIONS TO BE TAKEN BEFORE USING HONEY

- Honey should not be mixed with hot foods
- Honey should not be heated

- Honey should not be consumed when working in hot environment where you are exposed to more heat
- Honey should never be mixed with rain water, hot and spicy foods, and fermented beverages like whisky, rum, brandy, ghee and mustard.
- Honey includes nectar of various flowers of which some may be poisonous. Poison has hot or ushant qualities. When honey is mixed with hot and spicy foods the poisonous properties get enhanced and cause imbalance of dashes

http://www.ayurhelp.com (2010)

PART – II

A) Studies related to radiation induced oral mucositis for head and neck cancer patients undergoing radiation therapy

Alison., M. et al (2002) conducted a study on complication of radiation therapy for head and neck cancers, the patient perspective, personal interviews were conducted with 33 individuals who had received radiation therapy for head and neck cancers. These individuals described their treatment experiences and identified the most troublesome and debilitating side effects of radiotherapy. Overall, lethargy and weakness, dry mouth, mouth sores and pain, taste changes and sore throat were the most frequently reported troublesome or debilitating side effects. The single most debilitating side effect was oropharyngeal mucositis that was characterized by patients as sore throat and mouth sores and pain both negatively affected the patients to experience significant weight loss. As a conclusion trends toward more aggressive management of head and neck cancers under the need for

new and effective therapies for oropharyngeal mucositis occurring in patients receiving radiotherapy.

Hong., J.P. et al (2005) conducted a study to evaluate the wound healing effect of human recombinant epidermal growth factor in treatment of radiation induced severe oral mucositis in patients with head and neck malignancies. Patients at Asan Medical Center who had undergone definitive RT of the head and neck region with or without combined chemotherapy and who had developed severe oral mucositis were treated with topical rhEGF twice daily for 7 days. The evaluation of response with regard to oral mucositis was performed 1 week later. The result shows of the 11 treated patients, three had nasopharyngeal carcinoma, three had carcinoma of the oropharynx, two had carcinoma of the oral cavity, one had carcinoma of the hypopharynx and two had lymphoma of the head and neck. Six patients received RT only, and five patients received concurrent chemo radiotherapy. All patients showed improvements in their oral mucositis after topical treatment with rhEGF in that the Radiation Therapy Group grade was significantly decreases($p=0.0000$). As a conclusion this findings suggests that rhEGF is effective and safe for the treatment of radiation-induced mucositis.

Arun Maiya., et al. (2006) conducted a study on low level helium-neon (He-Ne) laser therapy in the prevention and treatment of radiation induced mucositis in head and neck cancer patients. The patients with carcinoma of oral cavity with stages II-IV a being uniformly treated with curative total tumor dose of 66Gy in 33 fractions over 6 wk were selected for the study. The study group patients were treated with (He-Ne) laser and control group patients were given oral analgesics, local application of anesthetic 0.9% saline and povidine wash during the

course of radiotherapy. The result shows a significant difference in pain and mucositis ($p<0.001$) between the two groups. At the end of radiotherapy mean pain score and mucositis grade were significant difference in pain and mucositis between two groups. As a conclusion the low level (He-Ne) laser therapy during radiotherapy treatment was found to be effective in preventing and treating the mucositis in head and neck cancer patients.

Chambers., M. S et al (2006) conducted a study to evaluated the effect of RK-0202, administered as an oral rinse, on the incidence of severe oral mucositis in patients being treated with of radiation therapy(RT) for tumors of the head and neck. The methods used was a prospective, randomized placebo-controlled, double blind study that compared the effect of 2 concentrations of RK-0202 with placebo on the incidence of severe oral mucositis at a cumulative RT dose of 60 Gy in 110 subjects. 27 subjects received RK-0202 5%, 38 received RK-0202 10%, 29 received placebo and 16 received standard of care. Oral mucositis was assessed twice weekly throughout RT by trained oral evaluators. The result shows the higher dose of RK- 0202 (10%) successfully attenuated severe oral mucositis as measured by WHO. The incidence of WHO grade 3 or 4 oral mucositis by a cumulative RT dose of 60 Gy was 35% in the RK-0202 group vs 54% in the placebo group. The over all incidence of serious adverse events was significantly lower in subjects treated with RK-0202 (5%). In general, there was no benefit noted among subjects who received RK-0202 as a 5% solution. As a conclusion RK-0202 significantly reduce the incidence of severe mucositis in subjects treated with radiotherapy for head and neck cancer and was not associated with significant adverse events.

Shanthi Appavu (2006) conducted a study on Nurses roles in the management and prevention of oral complications related to cancer treatment. Descriptive deign was adopted and convenience sampling was used in International cancer centre, Neyyoor. 118 patients admitted in oncology ward, medical ward and surgical ward of the hospital were interviewed including 40 staff nurses caring them on various aspects including management and prevention of oral complications related to cancer treatment. The results shows out of 118 patients 9 had developed complications. The over all prevalence rate was found to be higher in oncology ward (13.6%) as compared to medical ward (4.2%). In this study mouth was found to be the common complicated area during the treatment. The findings revealed that the majority of staff (67.5%) reported they give more important to oral mucositis. More than one third of the nurses had also reported that they inspect for local infection (37.5%), Xerostomia (37.5%), functional disabilities (15.0%), taste alteration (20.0%) and abnormal dental development (10.0%). As a conclusion there is a great need to educate not only nurses but relatives and the patients to adopt certain preventive strategies to reduce the prevalence of oral complications related to cancer treatment.

Rubina C. M., et al (2007) conducted a study on evaluation of some oral post radiotherapy sequelae in patients treated for head and neck tumors. One hundred patients (24 women, 76 men) ranging in age from 30 to 83 years (mean 59.2 years) were examined. Time since radiotherapy ranged from 1 to 72 months (mean 28 months). The total mean radiation dose received by the patient was 5, 955 CGY. The evaluation protocol included anamnesis, intraoral and extraoral examination, measurement of stimulated salivary flow and salivary PH symptoms reported by the patients included dry mouth (68%),

dysphagia (38%) and dysgeusia (30%). In 64% of the patient, the mean salivary flow rate was less than 0.7 ml/min. The mean salivary PH was 6.97 (± o.714) stimulated salivary flow increased with increasing post radiotherapy time (P< 0.05). As a conclusion the prevalence of mucositis was associated with higher radiation doses (P< 0.05) and the prevalence of atrophic candiadiasis was related to a longer post treatment period (P < 0.05)

Goyal. M et al (2009) conducted a study on oral mucositis in morning vs evening irradiated patients. The purpose of the study to evaluate prospectively the severity of acute oral mucositis in head and neck carcinoma patients irradiated in the morning (08.00 – 11.00h) versus late afternoon/evening (15.00–18.00h) . A total of 212 patients of head and neck carcinoma were randomized to morning (08.00- 11.00h) and evening (15.00 – 18.00h) groups. The grades of oral mucosa ulceration were compared in two groups. The results shows the grades of mucositis were marginally higher in the evening irradiated group than in the morning irradiated group 38%versus26% (P=0.08). In conclusion the observed incidence of grade III/IV mucositis in morning vs evening irriadiated patients may be because of the existence of circadian rhythm in the cell cycle of normal mucosa. This knowledge may provide a possibility of treating the patients with decreased toxicity to oral mucosa.

Castro., G. et al (2009) conducted a study to evaluate the efficacy of LLL (low level laser therapy) to decrease and is to evaluate the efficacy of LLL to decrease and delay severe oral mucositis and its impact on RT interruptions. In this prospective, randomized, double blind, phase III trial, patient were treated with either daily He-Ne LLL

2.5 J/cm2 or placebo laser. The result shows 73 patients were included 77% male, mean age 53years, primary site, oropharynx (31 patients), larynx (15patients), nasopharynx (10patients),hypopharynx (8 patients),oral cavity (7 patients), 36 patients received prophylactic LLL mean delivered RT dose (Gray) was higher in patients treated with LLL (69.3 VS 67.8, P=O,O4). As a conclusion LLL therapy was effective in reducing grade 3 or 4 oral mucositis and in reducing RT interruptions in these head and neck cancer patients treated with concurrent radiation therapy which is efficacy and tolerance.

Murphy., B. A. et al (2009) conducted a study on mucositis related morbidity and resource utilization in head and neck cancer patients receiving radiation therapy with or without chemotherapy. The objective of this study was to estimate health care resource utilization in head and neck cancer (HNC) patients. This was a prospective, longitudinal, multicenter, non interventional study of mucositis in patients receiving radiation with or without chemotherapy for HNC. Seventy five patients were enrolled from six centers–fifty (67%) patients received concurrent chemo radiation therapy, 34 (45%) received intensity-modulated radiation therapy. Over the course of the treatment, 57 (76%) patients reported severe mouth and throat soreness pain and functional impairment because of mouth and throat soreness increased during the course of therapy despite the use of opoid analgesics in 64 (85%) of the patients. As a conclusion this study demonstrates that mucositis related pain and functional impairment is associated with increased use of costly health resources. Effective treatments to reduce the pain and functional impairment of oral mucositis are needed in this patient population.

Zanin., J. et al (2010) conducted a study to evaluate quantitatively and qualitatively the effect of a 660-nm diode laser in the prevention and treatment of human oral mucositis in head and neck cancer patients undergoing radiation therapy. 72 patients with head and neck patients divided in to a control group (c; n=36) and a laser group (L; n=36). Laser therapy was performed in combination with radiotherapy and chemotherapy twice a week using a diode laser. The result shows statistically significant differences were observed between the two groups. Patients in group L usually did not present with OM ranging from level I to III associated with pain. As a conclusion laser therapy was effective in preventing and treating oral effects induced by radiotherapy and chemotherapy, thus improving the patient's quality of life.

Section B: Studies related to complementary and alternative therapy in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy

Nikolettti., S et al (2005) conducted a study to evaluate the effect on mucositis and to determine patients perception of the two forms of oral cryotherapy. A randomized, controlled, crossover trial was conducted in the out patient department in perth, Western Australia. Patients were randomized to receive each of three interventions. Standard care alone, standard care plus plain ice and standard care plus flavored ice. Oral mucositis was assessed by oral assessment guide and Western Consortium Cancer Nursing Research Scale. The findings shows from 67 patients revealed that when participants used standard care alone, there were significantly more likely to experience symptoms of mucositis than when they used either plain or flavored ice. The two

main concerns reported were the taste of flavored ice and the time required to complete the cryotherapy intervention. Side effects such as nausea, sensitivity and headache were reported more frequently for flavored ice (n=11),compared with plain ice (n=5), and standard care (n=1). As a conclusion both forms oral cryotherapy were effective in reducing the severity of oral mucositis and were more effective than standard care alone. flavored ice was associated with the highest frequency of side effects

Debra., L. (2006) conducted a study on a systemic review of randomized controlled trials (RCTS) evaluating alternative and complementary therapies for cancer related pain. Eighteen trials were identified with a total of 1,499 patients median sample size was 53 patients and the median intervention duration was 45 days. All studies were from single institutions, four had sample size justification and none reported any adverse effect. Seven trials reported significant benefit for the following CAM therapies, acupuncture(n=1), support groups(n=2), hypnosis(n=1), relaxation/imagery(n=2), herbal supplement(n=1). Four studies reported to benefit to CAM interventions, music (n=2), massage (n=2) in reducing cancer pain compared with a control arm. As a conclusion CAM interventions for cancer pain with adequate power, duration and sham control.

Alterio., D. et al (2006) conducted a study to assess feasibility, pain relief and toxicity tetracaine based oral gel in the treatment of radiotherapy (RT) induced oral mucositis. 50 patients treated with RT for head and neck cancer with clinical evidence of acute oral mucositis of grade >or=2 were scheduled to receive the tetracaine gel. A questionnaire evaluating the effect of the gel was given to all subjects.

The result shows in 38 patients (79.2%) a reduction in oral cavity pain was reported. 34 patients (82.9%) reported no side effects. 71% of patients had no difficulties in gel application. Unpleasant taste of the gel and interference with food taste were noticed in 5(12%) and 16patients (39%) respectively. As a conclusion tetracaine oral gel administration seemed feasible and safe while reducing RT- induced mucositis related oral pain in a sizeable proportion of treated head and neck cancer patients.

King-fong et'al (2008) conducted a study to compare the efficacy of 0.2% chlorhexidine gluconate and 0.15% benzydamine hydrochloride oral rinses in alleviating irradiation oropharyngeal mucositis for patients with head and neck cancer. 14 subjects were randomly assigned to chlorhexidine (n=7) or benzydamine (n=7)from the first day to 2 weeks after the completion of radiotherapy subjects were evaluated twice weekly through days 1 to 64 using the WHO mucositis scale and the 10 cm visual analogue scale for mouth pain and dysphagia. In result chlorhexidine arm 4 subjects (57%) had grade 2 , 3 subjects (71%) had grade 2 and 2 subjects (29%) had grade 3 mucositis. In benzydamine arm 5 subjects (71%) had grade 2, 2 subjects (29%) had grade 3 mucositis ($p > 0.05$). As a conclusion a lessening of severity of oral mucositis, pain, dysphagia for patients with head and neck cancer receiving benzydamine oral rinse.

Madankumar., P.D et al (2008) conducted a study to assess the effect of three alcohol free mouthwashes on radiation induced oral mucositis in patients with head and neck malignancies.80 patients with head and neck malignancies, scheduled to undergo curative radiotherapy were randomly assigned to receive one of the three

alcohol free test mouthwashes (0.12% chlorhexidine, 1% povidone iodine or salt/soda). The patients were instructed to rinse their with 10ml of the mouthwash, twice a day, for a period of 6 weeks. Mucositis was assessed by using WHO assessment scale. In results among 76 patients , patients in the povidone iodine group had significantly lower mucositis scores when compared to the control group from the first week of radiotherapy. Their score were also significantly lower when compared to the salt/soda and chlorhexidine group from the fourth and fifth week, respectively after radiotherapy. As a conclusion use of alcohol free povidone iodine mouthwash can reduce the severity and delay the onset of oral mucositis due to antineoplastic radiotherapy.

Ozlem., et al (2009) conducted a study to evaluate the prevalence of and factors related to the use of complementary and alternative medicine among cancer patients undergoing or following conventional treatment at the Erciyes University Oncology Hospital in Central Anatolia. Multivariate analysis was performed to compare the factors related to use of complementary and alternative medicine. A total of 268 consecutive cancer patients were enrolled in the study. Overall, 43% of the patients were using or had used complementary/alternative medicine. The result shows totally,90% of the patients using complementary/alternative medicine utilized herbs, and most of the herbs used were stinging nettle. Nearly half of the patients using complementary/alternative medicine (46.1%) were aiming to fight the disease. Among users, half of them regarded the method used as effective and 54(50.5%) suggested the use of complementary/alternative medicine to other patients. Only 23.1% of the patients discussed the use of complementary/alternative medicine with their physician. As a conclusion use of complementary/alternative

medicine among cancer patients in our center is modestly high, and the most common method is herbal therapy.

C. Studies related to Apitherapy in reducing oral mucositis in head and neck cancer patients undergoing radiation therapy

Rashad UM et al (2009) conducted a study on honey as topical prophylaxis against radiochemotherapy induced mucositis in head and neck cancer. The aim of the study is to evaluate the efficacy of pure natural honey as against radiochemotherapy induced mucositis. The study was done in Assiut university Hospital, Egypt between January 2005 and July 2006. 40 patients diagnosed with head and neck cancer were entered into the trial. Enrolled patients were randomized to either the treatment group, receiving concomitant chemotherapy and radiotherapy plus prior topical application of pure honey, or the control group, receiving concomitant chemotherapy and radiation therapy without honey. Patients were evaluated clinically every week to assess development of radiation mucositis. In the results in the treatment group, no patients developed grade four mucositis and only 3 patients(15%) developed grade three mucositis. In the control group 13 patients (65%) developed grade three or four mucositis ($p< 0.05$). As a conclusion this study shows that prophylactic use of pure natural honey was effective in reducing mucositis resulting from radiochemotherapy in patients with head and neck cancer.

Biswal., et 'al (2003) conducted a study on topical application of honey in the management of radiation mucositis. The aim of the study was to evaluate the effect of pure honey on radiation induced mucositis. 40 patients diagnosed with head and neck cancer requiring radiation to

the oropharyngeal mucosal area were divided into two groups to receive either radiation alone or radiation plus topical application of pure natural honey. Patients were treated using a 6 mv linear accelerator at a dose rate of 2 Gray per day five times a week up to a dose of 60 – 70 Gray. In this study arm, patients were advised to take 20 ml of pure honey 15 min before, 15 min after and 6 h post radiation therapy. Patients were evaluated every week for the development of radiation mucositis using the radiation therapy oncology group (RTOG) grading system. The main result of the study was there was significant reduction of symptomatic grade ¾ mucositis among honey–treated patients compared to controls i,e 20% vs 75% (p 0.00058). The compliance of honey treated group of patients was better than controls. As a conclusion topical application of natural honey is a simple and cost- effective treatment in radiation mucositis.

Apitherapy News (2008) the aim of the study is to evaluate the effect of pure natural honey on radiation induced mucositis. In this randomized single blind (examiner blind) clinical trial 40 patients with head and neck cancer requiring radiation to the oropharyngeal mucosa were randomly assigned to two groups. Twenty patients assigned to the study group received honey, while both the study and control groups received standard head and neck radiation therapy based on a standard protocol. In the study group patients were instructed to take 20 ml of honey 15 minutes before radiation therapy, then again at the interval of 15 minutes and six hours after radiation. In control group patients were instructed to rinse with 20 ml of saline before and after radiation. Patients were evaluated weekly for progression of mucositis using the oral mucositis assessing scale (OMAS). Result shows a significant reduction in mucositis among honey received patients compared with

controls (p = o.ooo) occurred. As a conclusion within the limits of this study the results showed the application of natural honey is effective in managing radiation induced mucositis.

Ahmad Zakaria., et al (2003) conducted a study on honey treatment for prevention of oral mucositis and gingivitis. Thus 20 – 40% of all cancer patients receiving intensive chemotherapy suffer from mucositis, the number climbs to 80% when chemotherapy and radiation are combined, and staggers even higher in patients receiving treatment for cancer in the head and neck area. The Biswal et' al investigated the use of honey in 40 adult patients with head and neck cancer. Patients consumed 20 ml (one and one- third teaspoon) of pure honey 15 minutes before, 15 minutes after and 6 hr post – treatment. There was significant reduction in the symptomatic grade three-four mucositis among honey treated patients compared with controls i,e 20% versus 75% ($p < 0.001$). In result the compliance of the honey treated group of patients was better than control. A total of 55% patients treated with topical honey showed no change or a positive gain in body weight compared with a positive gain in body weight compared with only 25% in the control arm($P = 0.05$). As a conclusion honey has potential for the treatment of periodontal diseases, mouth ulcers and other problems of oral health and a trial has demonstrated a statistically significant difference between chewing gelled honey and chewing gum in decreasing the number of bleeding sites on gums with gingivitis.

Khanal., et al (2010) conducted a study on effect of topical honey on limitation of radiation-induced mucositis. A single blind, randomized, controlled clinical trial was carried out to compare the mucositis limiting qualities of honey with lignocaine. A visual assessment scale permitted scoring of degrees of mucositis and

statistical evaluation. The result shows only 1 of 20 patients in the honey group developed intolerable oral mucositis compared with lignocaine group, indicating that honey is strongly protective (RR=0.067) against the development of mucositis. The proportion of patients with intolerable oral mucositis was lower in the honey group and this was statistically significant (p=0.000). As a conclusion honey applied topically to the oral mucosa of patients undergoing radiation therapy appears to provide a distinct benefit by limiting the severity of mucositis.

CHAPTER - III

RESEARCH METHODOLOGY

This chapter deals with the Research approach, Research design, setting of the study, population, sampling technique, sample size, sampling criteria, instrument and scoring procedure, validity, reliability, pilot study, data collection procedure and plan for data analysis.

RESEARCH APPROACH:

The Evaluative approach was used to evaluate the effectiveness of Apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy.

RESEARCH DESIGN:

The Research design used in this study was pre experimental non equivalent control group after only design.

Group	**intervention**	**Post test**
Experimental group	X	O1
Control group	-	O 2

X = Administration of Apitherapy to the head and neck cancer patients before and after radiation therapy in Experimental group.

01 = Post test to evaluate the effectiveness of Apitherapy in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy in experimental group.

02 = post test to assess the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy in control group.

SETTING OF THE STUDY:

The study was conducted in Erode cancer centre for experimental group and Human care global (HCG) centre for control group at Erode. The Erode cancer centre is a 50 bedded hospital and has 2 floors, specialized in oncology, providing chemotherapy, radiation therapy and surgical treatment to cancer patients. The HCG cancer center campus is situated with in senthil multi specialty hospital which is a 150 bedded hospital specialized in medical, surgical, neurology, nephrology, obstetrics and gynecology and oncology care to the sick patients. In the oncology ward they are providing radiation therapy, chemotherapy and surgical treatment to the cancer patients. In Erode cancer centre around 100 cancer patients and in HCG cancer center around 80 cancer patients are undergoing radiation therapy daily. Among those cancer patients 50 patients are diagnosed as head and neck cancer and undergoing radiation therapy daily respectively in both cancer centers.

POPULATION:

The target population of the study is head and neck cancer patients undergoing radiation therapy in selected cancer centers at Erode

SAMPLE:

The sample consists of head and neck cancer patients undergoing 2nd phase of radiation therapy.

CRITERIA FOR SAMPLE SELECTION:

INCLUSION CRITERIA:

- Both female and male patients undergoing radiation therapy in out patient department

- Head and neck cancer patients with the age group of 25 – 65yrs
- Head and neck cancer patients undergoing radiation therapy continues for 14 days
- Head and neck cancer Patients who understand, speak Tamil and English
- Head and neck cancer patients who are all willing to participate in this study.

EXCLUSION CRITERIA:

- Head and neck Cancer patients with Diabetes mellitus
- Head and neck Cancer patients who are critically ill

SAMPLE SIZE:

Sample size is 60. Among 6o Head and neck cancer patients 30 were in experimental group and 30 were in control group.

SAMPLING TECHNIQUE:

Purposive sampling technique was used to select the samples for the study. For experimental group patients were selected from Erode cancer Center and for control group patients were selected from HCG cancer Center at Erode.

INSTRUMENT AND SCORING PROCEDURE:

The instrument consist of three parts:

Part – I :

Section A

Demographic variables of the head and neck cancer patients were age, sex, education, occupation, family monthly income, marital status, area of residence, religion, diagnosis, duration of illness and duration of treatment.

Part – II

Section A: Western Consortium for Cancer Nursing Research (WCCNR) scale to assess the anatomical changes associated with oral mucositis

Section B: Observational check list was used to assess the functional abilities after apitherapy among head and neck cancer patients undergoing radiation therapy.

SCORING PROCEDURE:

Section A : The WCCNR scale has 4 grades as follows:

0 = None,

1 = Mild oral mucositis,

2 = Moderate oral mucositis,

3 = Severe oral mucositis

Section B: The observational check list consists of 10 dichotomous, questions for the right answers score" " one" is given, for the wrong answer score " zero "is given. The total score is 10.

0 - No oral mucositis

1-3 - Mild oral mucositis

4-6 - Moderate oral mucositis

7-10 - Severe oral mucositis

Total final score interpretation as follows:

Grade	Score	Percentage
No oral mucositis	0	0
Mild oral mucositis	1-4	1 - 30
Moderate Oral mucositis	5-9	31 - 70
Severe oral mucositis	10-13	71 – 100

VALIDITY:

The validity of the tool was established in consultation with 4 nursing experts and one medical oncologist. There was no changes made in the standardized tool (WCCNR SCALE).

RELIABILITY:

The reliability of the observational check list tool was established by testing for stability and internal consistence. The stability was assessed by using inter rater reliability method and Karl Pearson coefficient formula was used. The value found to be reliable(r=0.9). Internal consistency was assessed by split half method were spearman's brown prophecy was used. The value was found to be reliable(R= 0.8).

PILOT STUDY:

The pilot study was conducted in Human Care Global (HCG) cancer center at Erode. The investigator obtained written permission from the medical oncologists and oral permission was obtained from each participant prior to the study. The purpose of the study was

explained to each subjects prior to the study. Head and Neck cancer patients with first day of 2nd phase (on 23 rd day) of radiation therapy were selected as a study samples by using purposive sampling technique. For the experimental group and control group 6 cancer patients were selected respectively. In experimental group before 15 minutes of radiation therapy, 20ml of pure honey (apitherapy) was orally given to the patients to swish 20 ml of honey for 5 minutes then swallow it, again after 15 minutes of radiation therapy 20ml of pure honey (apitherapy) was orally given to the patients, ask the patient to swish 20 ml of honey for 5 minutes then swallow it, and advised the patient to repeat the same in their homes after six hours of radiation therapy. Apitherapy given daily from first day of 2nd phase of radiation therapy to last day of 3rd phase of radiation therapy(on 36th day)[about 14 days]. Where as in control group patients were treated as per hospital schedule. In both group post test was done at the end of the 3rd phase on 14th day by using WCCNR scale and by observational check list. Data was collected, analyzed and evaluated. The post test mean score for experimental group was 4(SD±0.9) and for the control group mean score was 8.7(SD±0.6) The "t" value is 11.13 is greater than the table value (1.96) which is significant at 0.05 level level of significance. After the pilot study it was found that it was feasible and practicable to conduct the main study.

DATA COLLECTION PROCEDURE:

The main study was conducted in selected cancer centers at Erode for the period of 5 weeks. The investigator obtained written permission from the medical oncologists in both cancer centers and oral permission was obtained from each participant prior to the study. The purpose of the study was explained to each subjects prior to the study. Head and

Neck cancer patients with first day of 2nd phase of radiation therapy were selected as a study samples by using purposive sampling technique. Per day five patients selected respectively in both cancer centers. For the experimental group 30 samples selected from Erode Cancer Center and for control group 30 samples selected from HCG Cancer Center at Erode. In experimental group before 15 minutes of radiation therapy, 20ml of pure honey (apitherapy) was orally given to the patients to swish 20 ml of honey for 5 minutes then swallow it, again after 15 minutes of radiation therapy 20ml of pure honey (apitherapy) was orally given to the patients to swish 20 ml of honey for 5 minutes then swallow it, and advised the patient to repeat the same in their homes after six hours of radiation therapy. Apitherapy given daily from first day of 2nd phase(from 23rd day) of radiation therapy to last day of 3rd phase of radiation therapy (upto 36th day)[about 14 days]. Where as in control group patients were treated as per hospital schedule. In both group post test done at the end of the 3rd phase (on 14th day) by using WCCNR scale and by observational check list. Data was collected and analyzed by using descriptive statistics and inferential statistics and the effectiveness was evaluated.

PLAN FOR DATA ANALYSIS

S.NO	DATA ANALYSIS	PURPOSE
1. Descriptive Statistics	➢ Frequency, Percentage	To describe the demographic variables of head and neck cancer patients undergoing radiation therapy.
	➢ Mean and Standard deviation	To assess the degree of oral mucositis after Apitherapy between experimental group and control group.
2.Inferential statistics	➢ Un-paired " t " test	To compare the effectiveness of Apitherapy in reducing oral mucositis between experimental group and control group
	➢ Chi – square test	To find the association of degree of oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental group.

PROTECTION OF HUMAN SUBJECTS

The research proposal was approved by the dissertation committee prior to conducting the pilot study and main study. The written permission was obtained from the medical oncologist and oral consent of each subject was obtained before starting the data collection. Assurance was given to them and confidentiality was maintained throughout the study.

CHAPTER – IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and interpretations of the data collected to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy.

The data obtained were analyzed and presented under the following headings.

ORGANISATION OF DATA

Section A : Assess the demographic variables in experimental and control Group

Section B: Assess the post test degree of oral mucositis in experimental and control group

Section C: Compare the effectiveness of apitherapy in reducing oral mucositis between experimental group and control group

Section D : Association of degree of oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy with selected demographic variables in experimental group.

Section A : **DISTRIBUTION OF DEMOGRAPHIC VARIABLES**

Table 1 Frequency and percentage distribution of demographic variables of head and neck cancer patients undergoing radiation therapy in experimental group and control group

n= 60

Sl. No	Demographic Variables	Experimental Group		Control group	
		f	%	No	%
1	**Age (In Years)**				
	30 – 40	3	10	3	10
	41 – 50	9	30	7	23
	51 – 60	7	23	6	20
	> 61 years	11	37	14	47
2	**Sex**				
	a) Male	22	73	24	80
	b) Female	8	27	6	20
3	**Education**				
	a) No formal Education	12	40	14	47
	b) Primary Education	12	40	10	33
	c) High school Education	5	17	4	14
	d) Higher secondary Education	1	3	1	3
	e) Degree	0	0	1	3
4	**Occupation**				
	a) Coolie	12	40	9	30
	b) House wife	5	16	7	23
	c) Self employee	9	30	4	13
	d) Government employee	2	7	2	7
	e) Un employee	2	7	8	27

4	**Marital status**				
	a) Un Married	0	0	0	0
	b) Married	28	93	27	90
	c) Widow	2	7	3	10
	d) Divorce	0	0	0	0
6	**Family Monthly Income**				
	a) Rs.1000 – Rs. 3000	6	20	4	13
	b) Rs.3001 – Rs. 6000	14	47	20	67
	c) Rs. 6001 – Rs. 9000	7	23	5	17
	d) > 9001	3	10	1	3
7	**Area of Residence**				
	a) Urban	5	17	12	40
	b) Rural	25	83	18	60
8	**Religion**				
	a) Hindu	23	77	20	67
	b) Muslim	3	10	3	10
	c) Christian	4	13	7	23
	d) Others	0	0	0	0
9	**Diagnosis**				
	a) Oral cancer	9	30	6	20
	b) Tongue cancer	10	33	11	37
	c) Throat cancer	8	27	12	40
	d) Brain cancer	3	10	1	3
10	**Duration Of Illness**				
	a) 0 – 1 year	30	100	30	100
	b) 2 – 3 years	0	0	0	0
	c) > 4 years	0	0	0	0

11	**Duration Of Treatment**				
	a) 0 – 1 year	30	100	30	100
	b) 2 – 3 years	0	0	0	0
	c) > 4 years	0	0	0	0

Table 1 showed distribution of head and neck cancer patients according to their age group depicts in experimental group the highest percentage 11(37%) of patients belonged to the age group of above > 61years, 9 (30%) were in the age group of 41-50 years, 7 (23%) were in the age group of 51-60 years and least 3 (10%) were in the age group of 30-40 years. In control group highest percentage 14 (47%) of patients belonged to the age group of above > 61years, 7(23%) were in the age group of 41-50 years, 6 (20%) were in the age group of 51-60 years and least 3 (10%) were in the age group of 30-40 years. In both groups it shows the most of the patients were above 61years of age (fig:2)

Percentage wise distribution of head and neck patient in experimental group according to their sex reveals the highest percentage 22(73%)were males, 8 (27%)were females. In control group highest percentage 24(80%)were males, 6 (20%)were females. (fig:3)

With regard to education in experimental group, majority of the head and neck cancer patients 12(40%) had no formal education, 12 (40%) had primary education and 5(17%) had high school education and 1(3%) had higher secondary education and none of them had degree education. In control group majority of the head and neck cancer patients 14 (47%) had no formal education, 10 (33%) had primary education and 4 (14%) had high school education and 1 (3%) had higher secondary education and 1 (3%) of them had degree education. (fig:4)

With regard to occupation in experimental group majority of head and neck cancer patients 12 (40%) were coolie workers, and 9 (30%) were self employee, 5 (16%) were house wife and 2 (7%) were government employee and 2 (7%) were un employee. In control group most of the patient 9(30%) were coolie workers, and 7 (23%) were house wife, 4 (13%) were self employee and 2 (7%) were government employee and 8 (27%) were un employee (fig:5)

With regard to marital status in experimental group most of the patients 28(93%) were married, 2 (7%) were widow and none of them were unmarried and divorced. In control group most of the patients 27(90%) were married, 3 (10%) were widow and none of them were unmarried and divorced. (fig:6)

With regard to family monthly income in experimental group majority of head and neck cancer patients 14(47%) were between Rs 3001– Rs 6000 and 7 (23%) were between Rs 6001 – Rs 9000, 6 (20%) were between Rs.1000-Rs. 3000 and least 3(10%) were in > Rs. 9001. In control group majority of head and neck cancer patients 20 (67%) were between Rs 3001– Rs 6000 and 5(17%) were between Rs 6001 – Rs 9000 and 4 (13%) were between Rs 1000 – 3000 and least 1 (3%) were in > Rs. 9001. (fig:7)

With regard to area of residence in experimental group majority of head and neck cancer patients 25 (83%) were from rural area and 5(17%) were from urban area. In control group majority of head and neck cancer patients 18(60%) were from rural area and 12(40%) were from urban area . (fig:8)

With regard to religion in experimental group majority of head and neck cancer patients 23(77%) were Hindus, and 4(13%) were Christians and 3 (10%) were Muslims and none of them belongs to other religion. In control group most of the head and neck cancer patients 20(67%) were Hindus, and 7(23%) were Christians and 3(10%) were Muslims and none of them belongs to other religion. . (fig:9)

With regard of diagnosis in experimental group majority of the head and neck cancer patient 10(33%) were diagnosed to have tongue cancer, 9 (30%) were diagnosed to have oral cancer, 8(27%) were diagnosed to have throat cancer, and 3 (10%) were diagnosed to have brain cancer. In control group majority of the head and neck cancer patient 12(40%) were diagnosed to have throat cancer, 11(37%) were diagnosed to have tongue cancer, 6(20%) were diagnosed to have oral cancer, and 1 (3%) were diagnosed to have brain cancer (fig:10)

With regard to Duration of illness in both groups majority of the head and neck cancer patients 30(100%) were between the year of 0-1 year. And none of them had the duration of 2-3 years and > 4 years.

With regard of Duration of treatment in both groups majority of the head and neck cancer patients 30(100%) were between the year of 0-1 year. And none of them had the duration of 2-3 years and > 4 years.

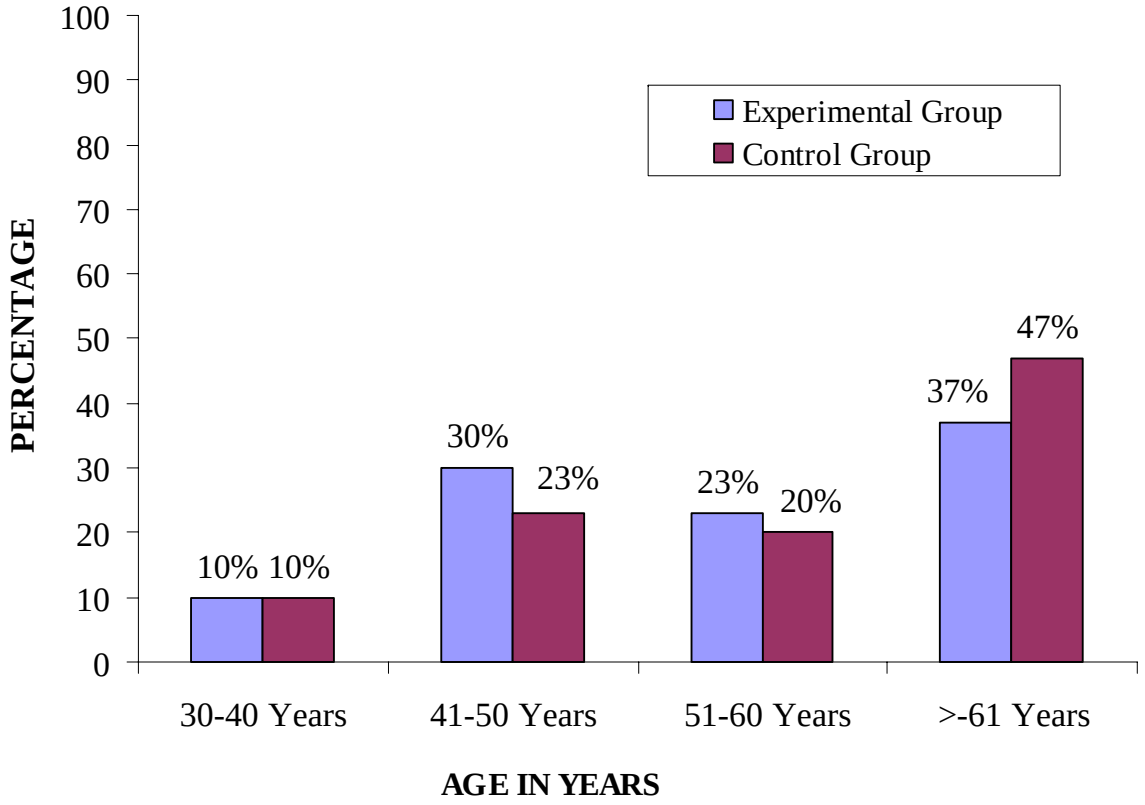

Fig: 2. Percentage distribution according to age of head and neck cancer patients undergoing radiation therapy in experimental and control group

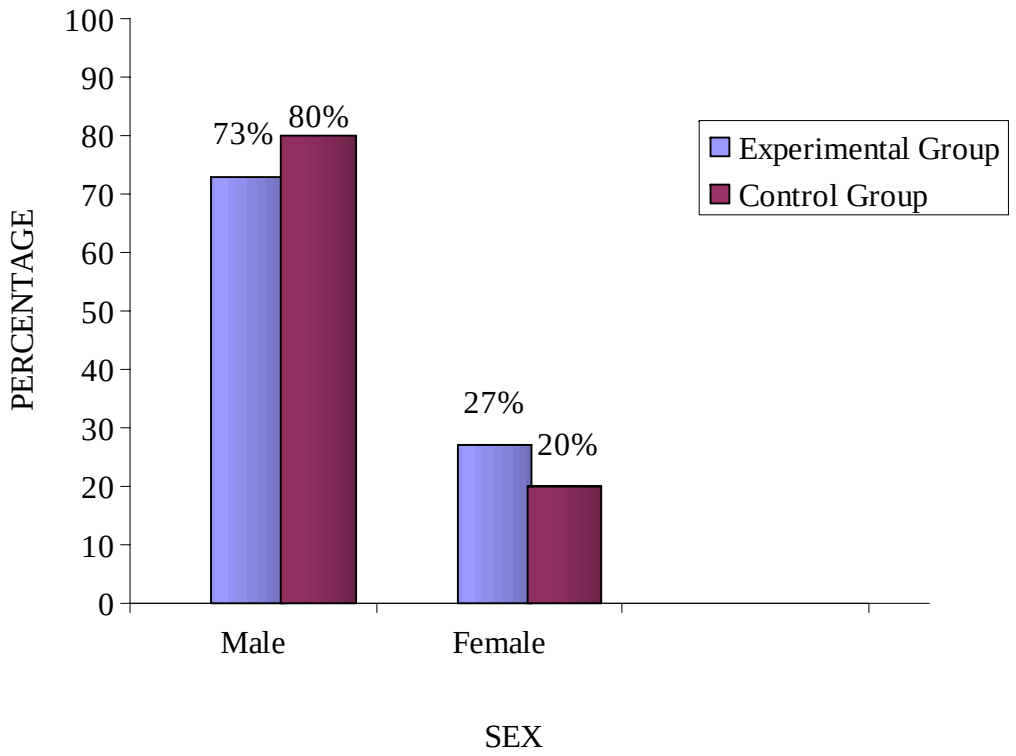

Fig: 3. Percentage distribution according to sex of head and neck cancer patients undergoing radiation therapy in experimental and control group

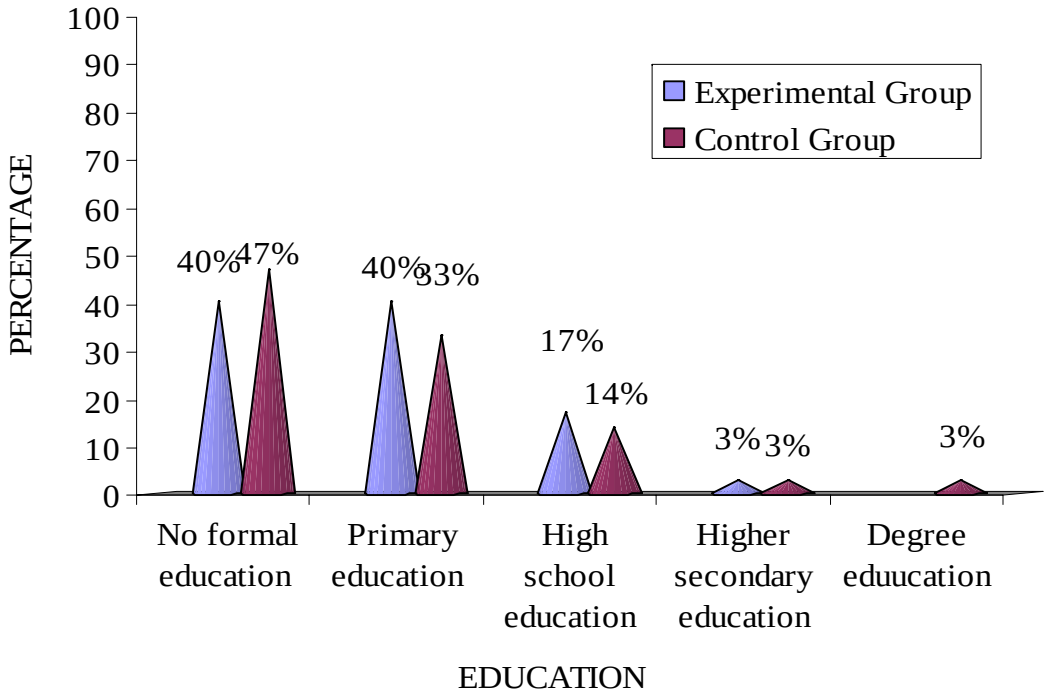

Fig: 4 Percentage distribution according to Education of head and neck cancer patients undergoing radiation therapy in experimental and control group

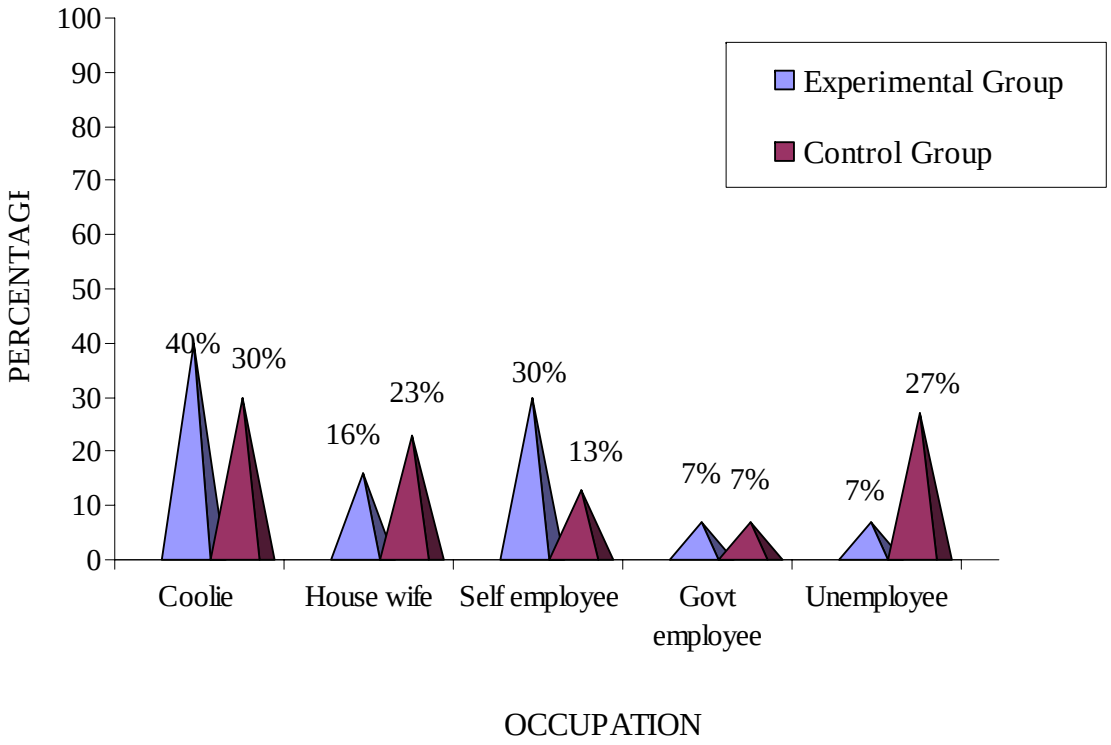

Fig: 5 Percentage distribution according to occupation of head and neck cancer patients undergoing radiation therapy in experimental and control group

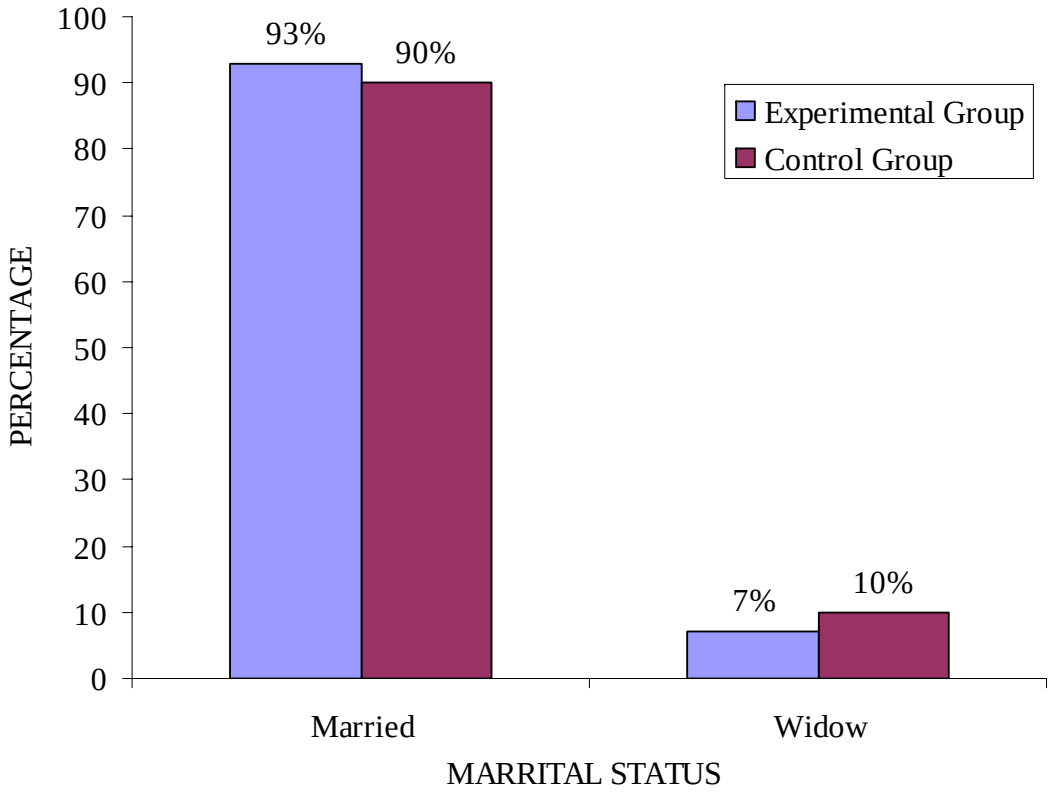

Fig: 6 Percentage distribution according to marital status of head and neck cancer patients undergoing radiation therapy in experimental and control group

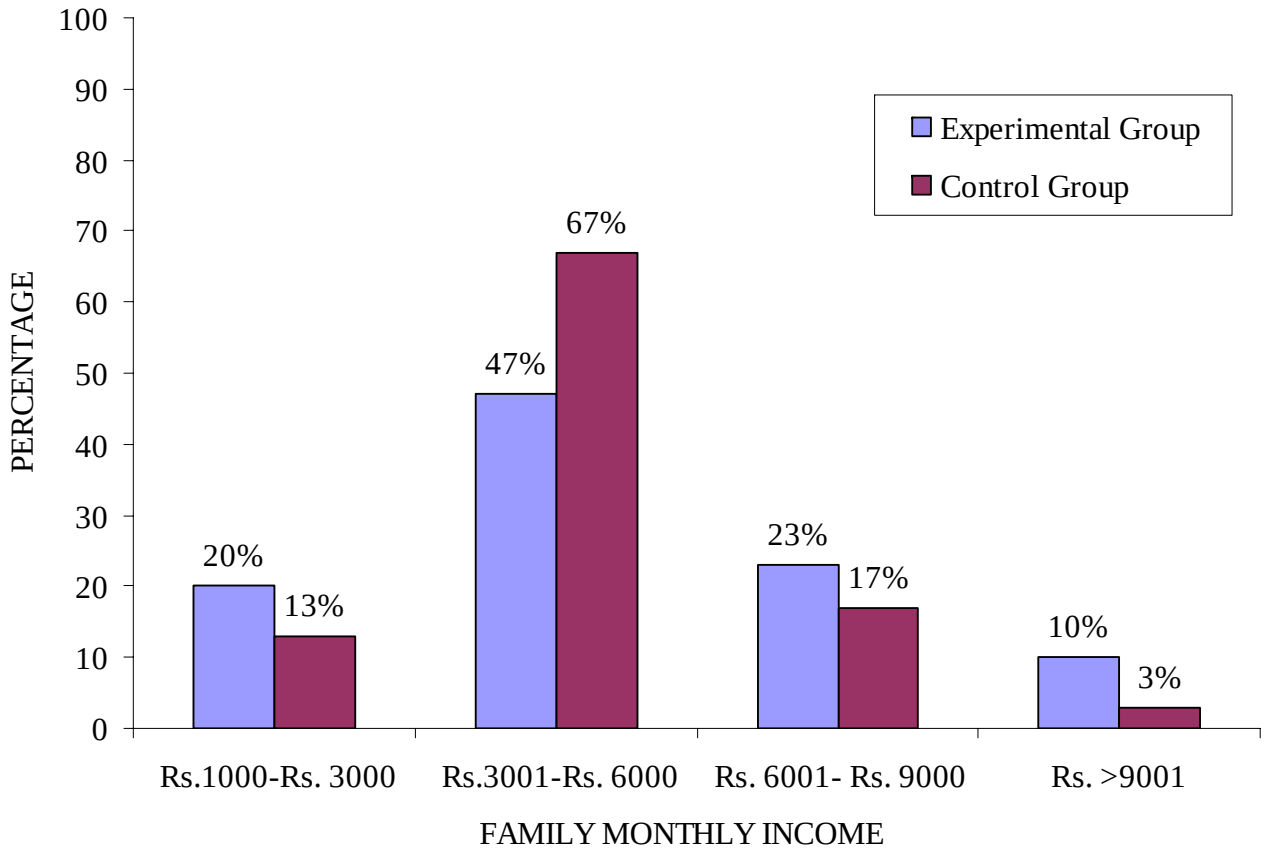

Fig: 7 Percentage distribution according to family monthly income of head and neck cancer patients undergoing radiation therapy in experimental and control group

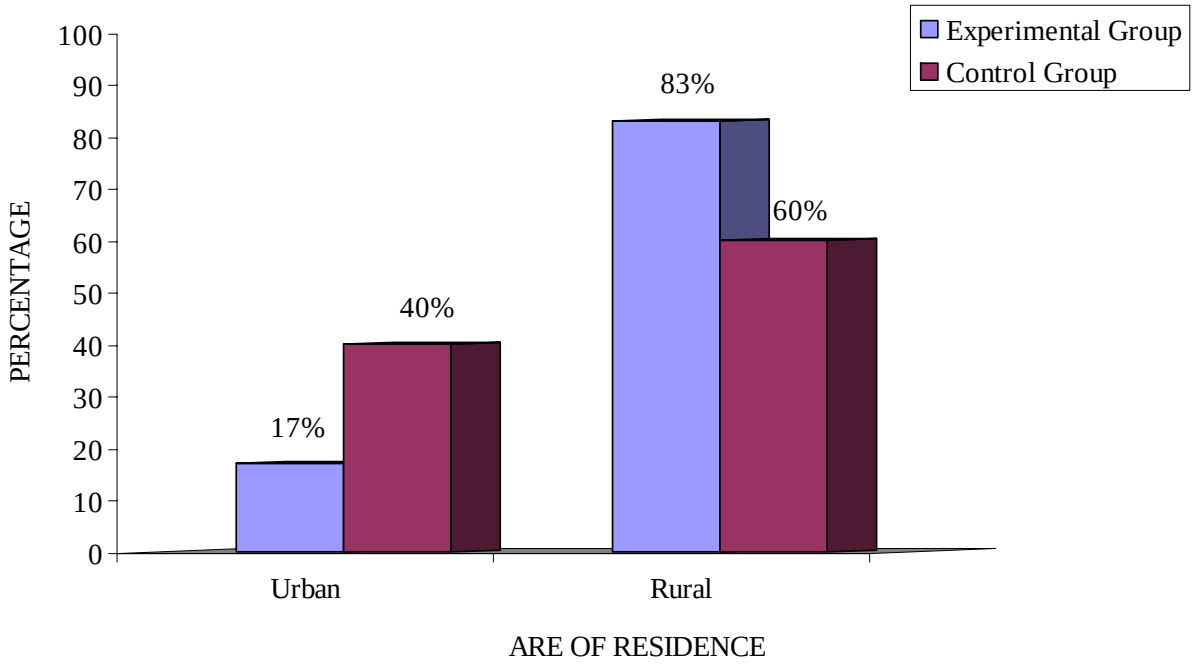

Fig 8 : Percentage distribution according to area of residence of head and neck cancer patients undergoing radiation therapy in experimental and control group

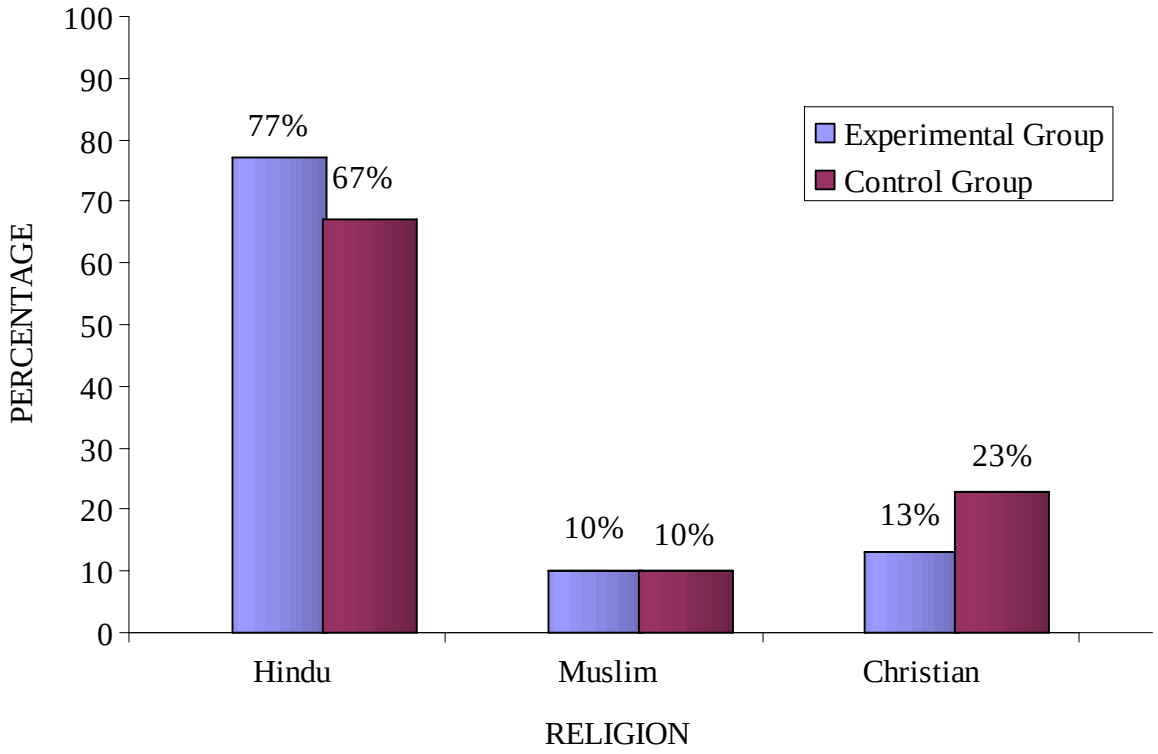

Fig 9 : Percentage distribution according to religion of head and neck cancer patients undergoing radiation therapy in experimental and control group

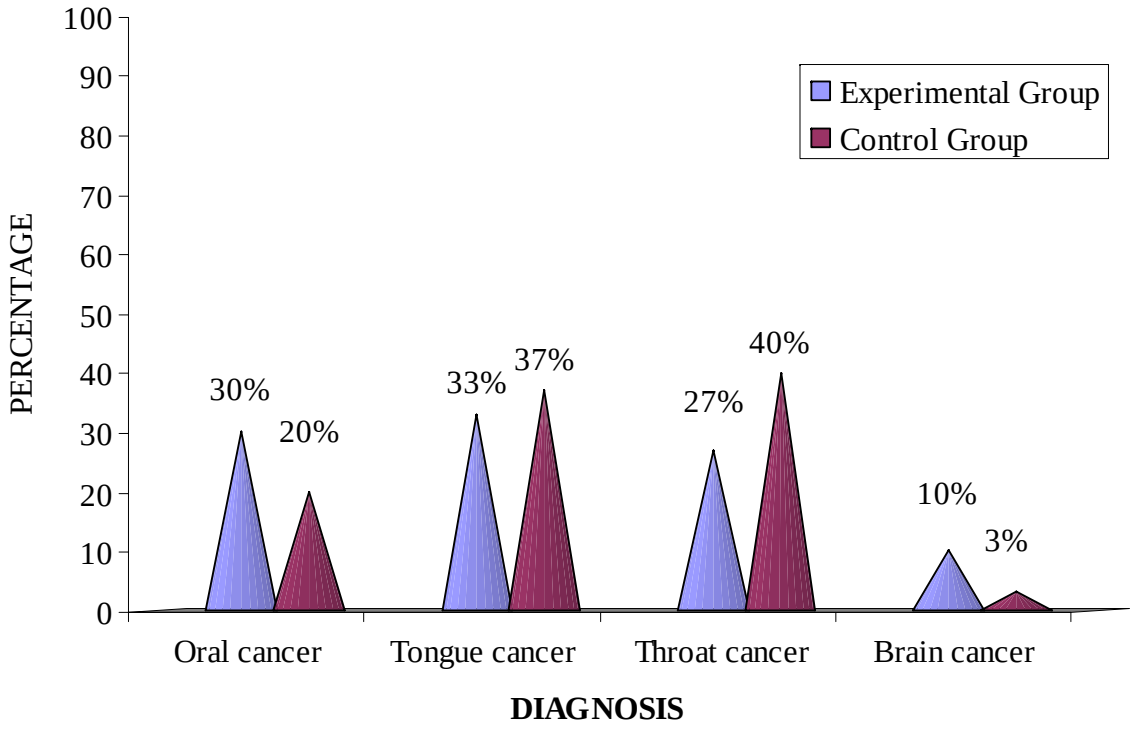

Fig 10 : Percentage distribution according to diagnosis of head and neck cancer patients undergoing radiation therapy in experimental and control group

SECTION B : ASSESS THE POST TEST DEGREE OF ORAL MUCOSITIS AFTER APITHERAPY IN EXPERIMENTAL GROUP AND CONTROL GROUP

Table: 2 Frequency and percentage distribution of degree of oral mucositis after apitherapy in experimental group and control group

n=60

Degree of oral mucositis	Experimental group		Control group	
	F	%	F	%
None	-	-	-	-
Mild	30	100	-	-
Moderate	-	-	11	37
Severe	-	-	19	63

Table (2) shows that majority of the head and neck cancer patients in experimental group 30(100%) of them had mild oral mucositis after apitherapy and none of them had moderate and severe oral mucositis respectively, where as in control group most of the head and neck cancer patients 19(63%) of them had severe oral mucositis, 11(37%) of them had moderate oral mucositis and none of them had mild oral mucositis.

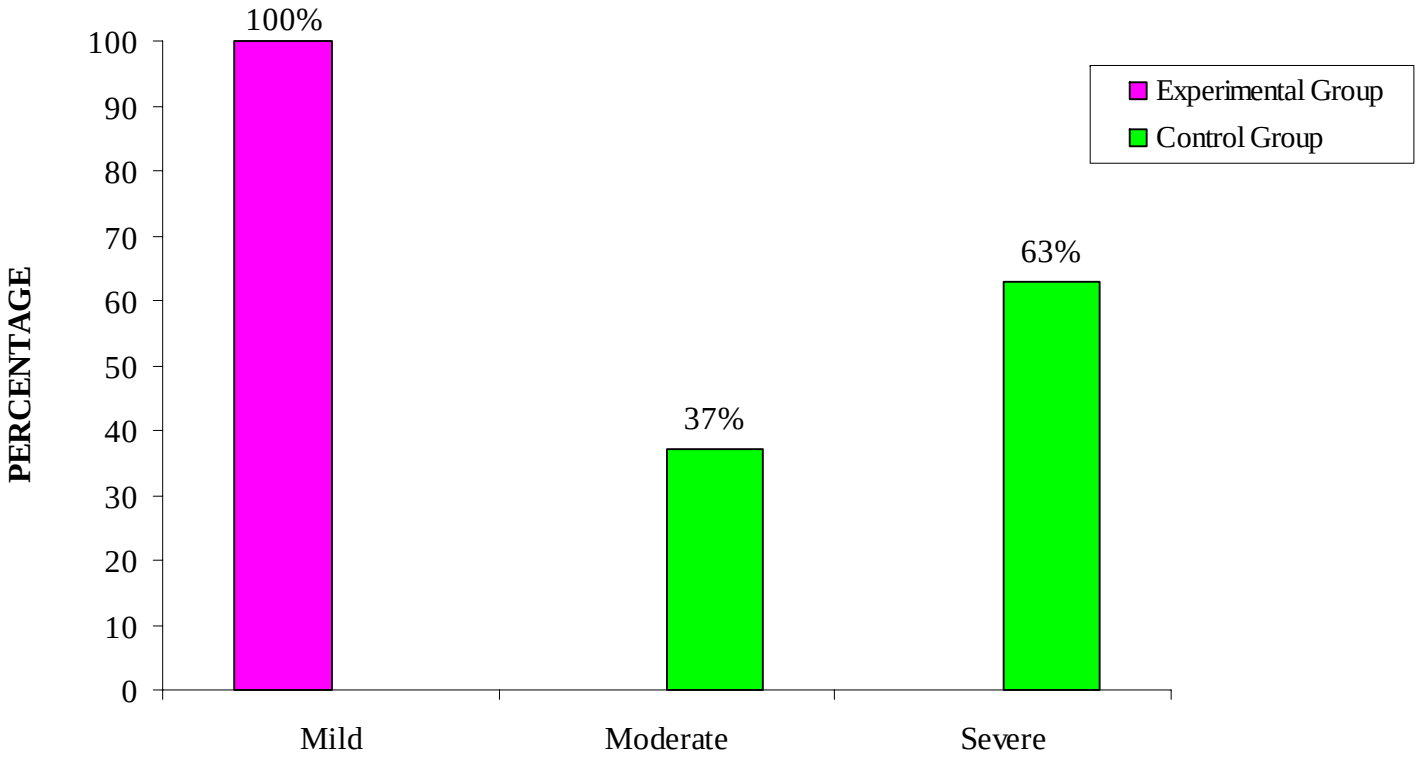

Fig 13 : Percentage distribution of post test Degree of oral mucositis after apitherapy in experimental group and control group .

Section C :

Comparison of the effectiveness of Apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy between experimental group and control group

Table : 3 Mean, standard deviation and " t " value of head and neck cancer patients undergoing radiation therapy between experimental group and control group.

n_1 = 30, n_2 = 30

Groups	Post Test Score		"t" Value	Table Value
	Mean	SD		
Experimental Group	4	1.74	7.93	1.96
Control Group	9	3.01		

df =58, (P< 0.05)

The Table (3) showed that post test mean score, standard deviation and independent "t" value of both groups.

The post test mean score of experimental group was 4 (SD ±1.74) and the control group mean score was 9 (SD ± 3.01). The "t" value is 7.93 is greater than the table value (1.96) which is significant at 0.05 level of significance shows there is a significant difference between degree of oral mucositis among head and neck cancer patients undergoing radiation therapy in experimental group comparing to control group

SECTION D : ASSOCIATION OF DEGREE OF ORAL MUCOSITIS AFTER APITHERAPY AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY WITH SELECTED DEMOGRAPHIC VARIABLES IN EXPERIMENTAL GROUP

Table 4 Association of degree of oral mucositis after Apitherapy among head and neck cancer patients undergoing radiation therapy with selected demographic variables in experimental group

n=30

S. No	Demographic Variables	Degree of oral mucositis						χ^2	Table value	Inference
		Mild		Moderate		Severe				
1	**Age (In Years)**									
	a) 30 – 40	3	10	-	-	-	-			
	b) 41 – 50	9	30	-	-	-	-			
	c) 51 – 60	7	23	-	-	-	-	4.66	7.815	NS
	d) > 61 years	11	37	-	-	-	-	df: 3		
2	**Sex**									
	a) Male	22	73	-	-	-	-	6.54	3.841	S
	b) Female	8	27	-	-	-	-	df : 1		
3	**Education**									
	a) No formal education	12	40	-	-	-	-			
	b) Primary education	12	40	-	-	-	-			
	c) High school education	5	17	-	-	-	-	11.86	9.488	S
	d) Higher secondary education	1	3	-	-	-	-	df: 4		
	e) Degree	0	0	-	-	-	-			

4	**Occupation**									
	a) Coolie	12	40	-	-	-	-			
	b) House wife	5	16	-	-	-	-			
	c) Self employee	9	30	-	-	-	-	13.07	9.488	S
	d) Government employee	2	7	-	-	-	-	df: 4		
	e) Un employee	2	7	-	-	-	-			
5	**Marital status**									
	a) Un Married	0	0	-	-	-	-			
	b) Married	28	93	-	-	-	-	22.6	7.815	S
	c) Widow	2	8	-	-	-	-	df: 3		
	d) Divorce	0	0	-	-	-	-			
6	**Family monthly income**									
	a) Rs.1000–Rs. 3000	6	20	-	-	-	-			
	b) Rs.3001–Rs. 6000	14	47	-	-	-	-	8.66	7.815	S
	c) Rs. 6001–R. 9000	7	23	-	-	-	-	df: 3		
	d) > 9001	3	10	-	-	-	-			
7	**Area of Residence**									
	a) Urban	5	17	-	-	-	-	13.4	3.841	S
	b) Rural	25	83	-	-	-	-	df: 1		
8	**Religion**									
	a) Hindu	23	77	-	-	-	-			
	b) Muslim	3	10	-	-	-	-	25.4	5.991	S
	c) Christian	4	13	-	-	-	-	df: 2		
	d) Others	0	0	-	-	-	-			
9	**Diagnosis**									
	a) Oral cancer	9	30	-	-	-	-			
	b) Tongue cancer	10	33	-	-	-	-	3.86	7.815	
	c) Throat cancer	8	27	-	-	-	-	df:3		NS
	d) Brain cancer	3	10	-	-	-	-			

Chi–square was calculated to find the association(table 4)of the degree of oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental group.

It revealed there was association was found between degree of oral mucositis of post test when compared to sex(χ^2=6.54), education(χ^2=11.86),occupation(χ^2=13.07),maritalstatus(χ^2=22.6), family monthly income(χ^2=8.66), area of residence(χ^2=13.4), religion(χ^2=25.4). However there was no association was found between degree of oral mucositis of post test when compared to age(χ^2=4.66) and diagnosis(χ^2=3.86) in experimental group.

CHAPTER – V

DISCUSSION

This chapter presents the interpretation of the statistical findings.

The aim of the study was to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy. A sample consist of 60 head and neck cancer patients undergoing radiation therapy who met the inclusion criteria were selected for the study by using purposive sampling method. Apitherapy given from 23rd day to 36th day(about 14 days). Post test done on 14 day by using WCCNR scale and by observational check list.

The findings of the study are discussed according to the objectives as followes:

1. To assess the post test degree of oral mucositis after apitherapy in experimental group and control group
2. To compare the effectiveness of apitherapy in reducing oral mucositis between experimental group and control group.
3. To find the association between degree of oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental group.

Description of the sample characteristics

The demographic characteristics of head and neck cancer patients are age, sex, education, occupation, marital status, family monthly income, area of residence, religion, diagnosis, duration of illness, duration of treatment.

Distribution of head and neck cancer patients according to their age group in experimental group depicts that the highest percentage 11(37%) of patients belonged to the age group of above > 61years, 9 (30%) were in the age group of 41-50 years, 7 (23%) were in the age group of 51-60 years and least 3 (10%) were in the age group of 30-40 years. In control group highest percentage 14 (47%) of patients belonged to the age group of above > 61years, 7(23%) were in the age group of 41-50 years, 6 (20%) were in the age group of 51-60 years and least 3 (10%) were in the age group of 30-40 years. In both groups it shows the most of the patients were above 61years of age (fig:2).

Percentage wise distribution of head and neck patient in experimental group according to their sex reveals the highest percentage 22(73%) were male, 8 (27%) were females. In control group highest percentage 24(80%) were male, 6 (20%) were females. (fig:3).

With regard to education in experimental group, majority of the head and neck cancer patients 12 (40%) had no formal education, 12 (40%) had primary education and 5 (17%) had high school education and 1 (3%) had higher secondary education and none of them had degree education. In control group majority of the head and neck cancer patients 14 (47%) had no formal education, 10 (33%) had primary

education and 4 (14%) had high school education and 1 (3%) had higher secondary education and 1 (3%) of them had degree education. (fig:4)

With regard to occupation in experimental group majority of head and neck cancer patients 12 (40%) were coolie workers, and 9 (30%) were self employee, 5 (16%) were house wife and 2 (7%) were government employee and 2 (7%) were un employee. In control group most of the patient 9(30%) were coolie workers, and 7 (23%) were house wife, 4 (13%) were self employee and 2 (7%) were government employee and 8 (27%) were un employee (fig:5).

With regard to marital status in experimental group most of the patients 28(93%) were married, 2 (7%) were widow and none of them were unmarried and divorced. In control group most of the patients 27(90%) were married, 3 (10%) were widow and none of them were unmarried and divorced. (fig:6).

With regard to family monthly income in experimental group majority of head and neck cancer patients 14 (47%) were between Rs 3001– Rs 6000 and 7 (23%) were between Rs 6001 – Rs 9000, 6 (20%) were between Rs.1000-Rs. 3000 and least 3(10%) were in > Rs. 9001. In control group majority of head and neck cancer patients 20 (67%) were between Rs 3001– Rs 6000 and 5(17%) were between Rs 6001 – Rs 9000 and 4 (13%) were between Rs 1000 – 3000 and least 1 (3%) were in > Rs. 9001. (fig:7).

With regard to area of residence in experimental group majority of head and neck cancer patients 25 (83%) were from rural area and 5 (17%) were from urban area. In control group majority of head and neck

cancer patients 18(60%) were from rural area and 12(40%) were from urban area. (fig:8).

With regard to religion in experimental group majority of head and neck cancer patients 23(77%) were Hindus, and 4(13%) were Christians and 3 (10%) were Muslims and none of them belongs to other religion. In control group most of the head and neck cancer patients 20 (67%) were Hindus, and 7(23%) were Christians and 3(10%) were Muslims and none of them belongs to other religion. . (fig:9).

With regard of diagnosis in experimental group majority of the head and neck cancer patient 10(33%) were diagnosed to have tongue cancer, 9 (30%) were diagnosed to have oral cancer, 8(27%) were diagnosed to have throat cancer, and 3 (10%) were diagnosed to have brain cancer. In control group majority of the head and neck cancer patient 12(40%) were diagnosed to have throat cancer, 11(37%) were diagnosed to have tongue cancer, 6(20%) were diagnosed to have oral cancer, and 1 (3%) were diagnosed to have brain cancer (fig:10).

With regard to Duration of illness in both groups majority of the head and neck cancer patients 30(100%) were between the year of 0-1 year. And none of them had the duration of 2-3 years and > 4 years.

With regard of Duration of treatment in both groups majority of the head and neck cancer patients 30(100%) were between the year of 0-1 year. And none of them had the duration of 2-3 years and > 4 years.

OBJECTIVE 1 To assess the post test degree of oral mucositis after apitherapy in experimental and control group

Among 60 head and neck cancer patients majority 30(100%) of them had mild oral mucositis and none of them had moderate and severe oral mucositis after the Apitherapy intervention in experimental group. Where as in control group majority of the head and neck cancer patients 19 (63%) of them had severe oral mucositis and 11 (37%) of them had moderate oral mucositis. This findings is consistent with the findings of **Rashad UM et ' al (2009)** conducted a study on honey as topical prophylaxis against radiochemotherapy induced mucositis in head and neck cancer. The aim of the study is to evaluate the efficacy of pure natural honey as against radiochemotherapy induced mucositis. In the results in the treatment group, no patients developed grade four mucositis and only 3 patients (15%) developed grade three mucositis. In the control group 13 patients (65%) developed grade three or four mucositis ($p< 0.05$). As a conclusion this study shows that prophylactic use of pure natural honey was effective in reducing mucositis resulting from radiochemotherapy in patients with head and neck cancer.

OBJECTIVE 2 To compare the effectiveness of Apitherapy in reducing oral mucositis between experimental and control group

Among 60 head and neck cancer patients the post test mean score of experimental group was 4 (SD ±1.74) and the control group mean score was 9 (SD ± 3.01). The "t" value is 7.93 is greater than the table value (1.96) which is significant at 0.05 level of significance shows there is a significant difference between degree of oral mucositis among head and neck cancer patients undergoing radiation therapy in experimental

group comparing to control group. This findings is consistent with the findings of **Biswa Mohan Biswal et ' al (2003)** conducted a study on topical application of honey in the management of radiation mucositis. The aim of the study was to evaluate the effect of pure honey on radiation induced mucositis. The main result of the study was there was significant reduction of symptomatic grade ¾ mucositis among honey – treated patients compared to controls. i,e 20% versus 75% (p 0.00058). The compliance of honey treated group of patients was better than controls. As a conclusion topical application of natural honey is a simple and cost- effective treatment in radiation mucositis. Hence H_1: There is a significant reduction in the degree of oral mucositis after Apitherapy among head and neck cancer patients undergoing radiation therapy between experimental group and control group was accepted.

OBJECTIVE 3

Association between degree of oral mucositis after Apitherapy among head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental group.

The findings of the study shows the association between degree of oral mucositis after Apitherapy among head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental group. There is a significant association between degree of oral mucositis of post test when compared to sex, education, occupation, marital status, family monthly income, area of residence and religion. However there is no significant association between degree of oral mucositis of post test when compared to age, diagnosis. This findings is consistent with the findings supported by a study conducted by **Norio Mitsuhashi, et'al (2008)** on cancer patients Aged 90

years or older. The aim of the study is to investigate the clinical efficacy of radiation therapy for cancer patients aged 60 years or older. The result showed eleven 11(79%) of the 4 patients with head and neck cancer were treated with curative intent. Radiation response without any severe complication was observed in 9 (90%) of the 10 patients with head and neck cancer treated with curative intent who finished treatment. The median survival time was 8 months in the 10 patients with head and neck cancer who completed treatment with head and neck cancer who completed treatment with curative intent. Complete response was achieved in all of the patients with skin cancer without any major sequelae. As a conclusion Age of 90 years or older is not a limiting factor for radiation therapy. The population aged 65 years or older has recently exceeded 14.8% of the Japanese population and will reach 27.4% in 2025. The mean life expectancy in Japan became 77,2 years for male and 83.8 years for female persons in 1997 and is the longest in the world. In 1995, the percentages of male and female persons aged 90 years or older were 0.2% to 0.6% respectively. Hence H_2**:** There is a significant association between degree of oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental group was accepted.

CHAPTER – VI

SUMMARY, CONCLUSION, IMPLICATION, RECOMMENDATIONS AND LIMITATION

SUMMARY OF THE STUDY:

The aim of the study was to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy.

An evaluative study with pre experimental non equivalent control group post test only design was used for the study which was conducted in Erode cancer center and HCG cancer center at Erode. The study was based on modified widenbach's (1964) helping art clinical nursing theory that assesses the effectiveness through identifying of help, ministering the needed help and validating the need for help to achieve the necessary tool. The total sample of the study was 60 head and neck cancer patients undergoing radiation therapy. The Samples were selected by purposive sampling method who met the inclusion criteria. Among 60 head and neck cancer patients 30 patients for experimental group and 30 patients for control group. In experimental group Before 15 minutes and after 15 minutes of radiation therapy 20 ml of pure honey orally given to the patient to swish 20ml honey for 5 minutes then swallow it, and advised the patient to repeat the same in their home after 6 hours of post radiation therapy for 14 days. The post test done on 36th day by using WCCNR scale and by observational check list. The effectiveness of apitherapy was assessed by unpaired/independent "t" test. Chi-square test was used to find the association between degree of oral mucositis after apitherapy among

Head and neck cancer patients undergoing radiation therapy with their selected demographic variables in experimental group.

MAJOR FINDINGS OF THE STUDY

Distribution of demographic characteristics of head and neck cancer patients in experimental group and control group

- In experimental group majority of the head and neck cancer patients 11 (37%) belongs to the age group of > 61 years and in control group 14 (47%) belongs to the age group of > 61 years
- In experimental group majority of the head and neck cancer patients in experimental group 22 (73%) were male and in control group 24 80%) were male
- In experimental group majority of the head and neck cancer patients 12 (40%) of them had no formal education and had primary education and in control group 14 (47%) of them had no formal education
- In experimental group majority of the head and neck cancer patients 12(40%) were coolie workers and in control group 9(30%) were coolie workers
- In experimental group majority of the head and neck cancer patients 28 (93%) were married and in control group 27 (90%) were married
- In experimental group majority of the head and neck cancer patients 14 (47%) family income is Rs. 3001 – Rs. 6000 and in control group 20 (67%) family income is Rs. 3001 – Rs. 6000
- In experimental group majority of the head and neck cancer patients 25 (83%) were from rural area and in control group 18(60%) from rural area

- In experimental group majority of the head and neck cancer patients 23(77%) were Hindus and in control group 20 (67%) were Hindus
- In experimental group majority of the head and neck cancer patients 10 (33%) were diagnosed to have tongue cancer and in control group 12 (40%) were diagnosed to have throat cancer
- In both groups majority of the head and neck cancer patients 30(100%) had duration of illness of 0 – 1 year
- In both groups majority of the head and neck cancer patients 25 (100%) had duration of treatment of 0 – 1 year

➢ The post test degree of oral mucositis after apitherapy in experimental group and control group majority of the head and neck cancer patients in experimental group 30(100%) of them had mild oral mucositis after apitherapy and none of them had moderate and severe oral mucositis respectively, where as in control group most of the head and neck cancer patients 19(63%) of them had severe oral mucositis, 11(37%) of them had moderate oral mucositis and none of them had mild oral mucositis.

➢ The post test mean score of experimental group was 4 (SD ±1.74) and the control group mean score was 9 (SD ± 3.01). The "t" value is 7.93 is greater than the table value (1.96) which is significant at 0.05 level of significance shows there is a significant difference between degree of oral mucositis among head and neck cancer patients undergoing radiation therapy in experimental group comparing to control group

➢ There was association was found between degree of oral mucositis of posttest when compared to sex(χ^2=6.54), education(χ^2=11.86), occupation(χ^2=13.07),marital status(χ^2=22.6), family monthly income (χ^2=8.66), area of residence (χ^2=13.4), religion(χ^2=25.4).

- There was no association was found between degree of oral mucositis of post test when compared to age (χ^2=4.66) and diagnosis (χ^2=3.86) in experimental group.

CONCLUSION:

The present study to evaluate the effectiveness of apitherapy in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy. Based on statistical findings the post test mean score of experimental group was 4 (SD ±1.74) and the control group mean score was 9 (SD ± 3.01). The "t" value is 7.93 is greater than the table value (1.96) which is significant at 0.05 level of significance shows there is a significant difference between degree of oral mucositis among head and neck cancer patients undergoing radiation therapy in experimental group comparing to control group.

NURSING IMPLICATIONS

NURSING PRACTICE

- The nurses can develop the skill in providing necessary care to head and neck cancer patients in reducing oral mucositis by using apitherapy, as it help to reduce the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy.
- Apitherapy technique can be practiced in hospital settings as a evidence based practice in reducing the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy
- The findings will help the nursing profession to assess the effectiveness of apitherapy and could implement the apitherapy technique for head and neck cancer patients undergoing radiation therapy.

NURSING EDUCATION

- The nurse educator can provide in–service education to nursing personnel to update their knowledge about the apitherapy and its benefits to the head and neck cancer patients.
- Nursing students should be educated on apitherapy technique in reducing degree oral mucositis among head and neck cancer patients.
- The findings will help the student nurses to identify the apitherapy technique, and to be motivated in participating to reduce the degree of oral mucositis among head and neck cancer patients.
- The nurse educator can include Apitherapy technique as a means of non–pharmacological therapy in the curriculum, which can be adopted by the students and the nursing personals.

NURSING ADMINISTRATION

- The nurse administrator should conduct in–service education to disseminate the research findings through continuous nursing education to all nurses.
- Pamphlets, leaflet about apitherapy technique can be made available to nursing staff in the cancer wards and to nurse educators in nursing educational institution.
- Clinical nurses and nurse educators should be given education to update their knowledge on apitherapy technique.
- The findings will help the nurse administrator to take up an important role in implementing apitherapy technique in hospital settings.

NURSING RESEARCH:

- The findings of this study will help to motivate the nurses to conduct research about apitherapy technique in future.
- This study is the foundation to conduct study on larger population to strongly prove the efficacy of apitherapy technique on reducing oral mucositis among head and neck cancer patients undergoing radiation therapy.
- The findings can be utilized for further research in head and neck cancer with oral mucositis.

RECOMMENDATIONS

- A comparative study can also be done between the effectiveness of various non – pharmacological measures on reducing oral mucositis
- A comparative study can be conducted to evaluate the apitherapy practice in various cancer settings.
- The effect of apitherapy can be assessed in combination with other non pharmacological agents and various oral rinses for the good parturient outcome.

LIMITATION

- Since the understanding level of patients were different patients took more than 15 minutes to accept the intervention.

BIBLIOGRAPHY

BOOK REFERENCE

1. Basavanthappa, B. T. (2003) " Medical surgical nursing", (1st ed) New Delhi: Jaypee Brothers medical publishers (p) Ltd. P.P =635 – 638
2. Black, M . Joyce et. al (2005) ' Medical surgical nursing", (7th ed) Missouri, sounders. P.P=349-364,
3. Brockop, Y. Dorothy, et. al (2003) " Fundamental of nursing research" (3rded) USA, Jones and Bartlett publishers P.P =105 – 111
4. Gurumani, N,(2005) "An introduction to biostatistics", (2nd ed) New Delhi, MJP publishers (p) Ltd P.P =211 – 213, 347 – 369
5. Jaggi.O.P" Cancer causes, prevention, and treatment", orient paperbacks publication P.P= 99-106
6. Jarrelll stephens B, (1994) "Basic statistics", (1 ed) W.M.C Brown publishers, P.P =108 – 141.
7. Lewis, et. al, (2007) " Medical surgical nursing " 7th ed M issouri, Mosby publication, P.P 292 – 301
8. Phipps, Long and Woods, (1999) "Medical surgical nursing ", (7th ed) New Delhi B. J Publications pvt. Ltd, P.P =643 – 647.
9. Polit, F. denise and (2008) " Nursing Research", (5th ed) New Delhi, wolters kluwes (India) Pvt Ltd, P.P= 507 – 583.
10. Ram sharan Mehta (2007) "Oncology nursing", Jaypee brothers publication, New Delhi (p) Ltd, New Delhi. P.P=63-89, 297-326.
11. Reynolds, A. (1998), "Medical surgical nursing", 2ND edition , Jaypee brothers publication(p) Ltd P.P=247-251
12. Rick Daniels et.al (2007) "Contemporary medical surgical nursing",1st edition, sanat printers publication, Haryana P.P=129-130

13. Rose, A Gates,"Oncology nursing secrets, 1st edition(1997). Lordson publishers, (p) Ltd, Delhi P.P=135-145, 180-188.
14. Samant, K. (2002) Medical surgical nursing, 2nd edition, Vora medical publication at Mumbai P.P=237-250
15. Sandra M.Nettina, (1974) the Llippincott manual of nursing practice, 6th edition, Lippincott publication at Philadelphia Lippincott, P.P=469-476
16. Shafer's (1980) "Medical surgical nursing", 7th edition, B.I publications, Pvt Ltd, newdelhi P.P=587-590
17. Smeltzer C. Suzanne et. al "Text book of medical surgical nursing", (10th ed) Philadelphia P.P =1326 – 1340.
18. Susan C. dewit, Essentials of medical surgical nursing", 4th edition, W.B sounders company publications, P.P=206-230
19. Wesley (1994) "Nursing theories and models " , (2nd ed) Pennsylavian spring house corporation, P.P =46 – 51.
20. Williams s. Linda et " al " Medical surgical nursing " , (1ST ed) Philadelphia F. A Davis Company P.P =701 – 708

JOURNAL REFERENCE

21. Azzaz,. A.N (2002)"Cancer nursing: complication of radiation therapy for head and neck cancer" volume 123, p.p=1-5
22. Best practice, "Prevention and treatment of oral mucositis in cancer patients", volume 2, issue 3 vol 2, (1998), P.P=1-2
23. Gwede., C.K "Journal of pain and symptom management" (2009) vol 38. P.p = 522 – 532
24. John Hookins, (2008), "Cancer update", Nurses of India, vol:1, p.p=11-12

25. Manish Goyal (2009)"Oral mucositis in morning vs evening irradiated patients", the journal of supportive oncology, volume 85, Issue 6, P.P= 504-509
26. Motallebnejadn, M (2008) "Journal of contempary dental practice" vol 9, march 1 p.p 1 – 5
27. Rose ped A.M (2002) "Complications of radiation therapy for head and neck cancer", cancer nursing, P.P= 468-469
28. Shanthi appavu, (2008) " Nurses role in the management and prevention of oral complications related to cancer treatment", Indian Journal of holistic nursing vol : 4, p.p = 34 – 35.

NET REFERENCE

29. http. www.aolhealth.com/conditations/oral complications of radiation theraphy,
30. http: // apitherapy. Blogspot. Com (2008)
31. http. www.ayurhelp. Com/ articles/honey, htm
32. http:// www.beaumonthospitals.com/radiation therapy - head - neck - cancer
33. http://www.buzzle.com/oral mucositis/articles.htm
34. http:// www.cancer.med.umich.edu/cancertreat.shtml
35. http:// Cancer nursing: complication of radiation therapy for head and neck cancer (2002)
36. http:// clinical.gov/ct2/shoe NCT – 00615420
37. http:// www.cochranelibrary.com
38. http:// en.wikipedia.org/wiki/honey
39. http:// en.wiktionary.org/wiki/mucositis
40. http://linkinghub.elsevier.com
41. http ://manuka honey. com
42. http:// mhtml:file://C:/honey and its benefits.mht

43. http:// www. Honeymark prodect.com
44. http:// www.kepivance.com/oral mucositis/assessment
45. http:// www.ncbi.nim.nih.gov/pubmed
46. http:// www.oncolink.org/coping/article.cfm
47. http:// www.patient.co.uk/health/mouth-care.htm
48. http:// www. pt.co/health/mouth.care,htm
49. http:// pubmed – pain symptoms manage oct (2009)
50. www.va.gov/glossary.htm

APPENDIX - A

BISHOP'S COLLEGE OF NURSING
(C.S.I. Trichy - Tanjore Diocese)
C.S.I. Mission Compound, **DHARAPURAM** - 638 656,
Tirupur District.
☎ Off: **04258** - **221224**
223962
Fax : **04258 221224**
E - Mail; principalbcn@sify.com

Ref : BCN/IN/11/3/2010

Date 23.03.2010

To,

The Managing Director,
Erode Cancer Centre,
Velavan Nagar,
Perundurai Road,
Erode-9.

Respected Sir/Madam,

This is to certify that Mrs.D.Bharathi is a bonafide student of our college doing her M.Sc.,(N) programme II year. As part of her requirement under, The Tamil Nadu Dr.MGR. Medical University, Chennai, she has to do a project on " A Study to evaluate the effectiveness of api therapy in reducing oral mucositis among the cancer patients undergoing radiation therapy" .

Kindly permit her to carryout a study in your hospital.

Thanking you,

Yours faithfully,

PRINCIPAL,
BISHOP'S COLLEGE OF NURSING,
C.S.I. MISSION COMPOUND,
DHARAPURAM-638 656,
TIRUPUR DISTRICT

APPENDIX - A

HCG
adding life to years
South Asia's Largest Cancer Care Network

Cancer Center

Dr. P. Suthahar MDRT
Consultant Radiation Oncologist
Admin. In - charge

24.03.2010

To:
The Principal,
Bishops College of Nursing,
Dharapuram, Tirupur.

Dear Sir,

Sub: Permission to carry out research for **Mrs.D.Bharathi**, IInd year M.Sc Nursing student on "A study to evaluate the effectiveness of api therapy in reducing oral mucositis among the cancer patients undergoing radiation therapy" – **Reg**

Ref: Your letter No: BCN/115/1/3/2010 dated 23.03.2010

With reference to the above, the student is permitted to undergo research in our institute subject to the following terms and conditions:

1. From the discussion and presentation with the student, it was understood that the project duration is of one month. For a patient to complete radiation therapy it will need 6.3 weeks. With the above mentioned topic to complete the study it needs 7 weeks. So if you give 7 weeks, the study can be done.
2. They should abide by the hospital rules and regulations.
3. They should not unnecessarily interfere with patients

APPENDIX - B

LETTER SEEKING EXPERT'S OPINION FOR VALIDITY OF TOOLS

From

Mrs.D.Bharathi,
M . sc (Nursing) II year,
Bishop's College of Nursing,
Dharapuram.

To

Respected Madam / Sir,

Subject: Requisition for content validity of tool

I am one of the M.Sc (Nursing) second year student of Bishop's College of Nursing, Dharapuram, under Dr. M.G.R Medical University, Chennai. As a partial fulfillment of my M. Sc (N) Degree Programme, I am conducting a research on "**A study to evaluate the effectiveness of Apitherapy in reducing oral mucositis amoang cancer patients under going radiation therapy in Selected Cancer Centre at Erode**

I am sending the above stated for content validity and for your expert and valuable opinion.

I will be very thankful to return it to the undersigned

APPENDICE- C

LIST OF EXPERTS FOR VALIDITY OF THE TOOL

6. **Mrs. Sheela Rosalena ,**
   Principal,
   2/1, Kondapa Gardep,
   Jeeva Nagalli ,
   Bangalore – 56005.

7. **Mrs. Amirtha Shanthi,**
   Asso. Professor,
   Collegeof Nursing,
   PIMS ,
   Pondicherry .

8. **Mrs. Shobana ,**
   Asso. Professor,
   Annai JKK College of Nursing,

Kumarapalayam ,
Namakkal District – 638 183.

9. **Mr. Ananth,**
   Reader,
   Mahalingam College of Nursing,
   Sakthi Nagar,
   Bhavani.

5. **Dr.Natesan.,MBBS.,M.S.,Ortho.,D.Ortho,**
   Consultant Ortho Surgeon,
   LKM Hospital,
   Erode – 638 009**.**

APPENDIX - D

CERTIFICATE FOR VALIDITY

This is to certify that the project tool on ""A study to evaluate the effectiveness of Apitherapy in reducing oral mucositis among cancer patients undergoing radiation therapy in Selected cancer centers at Erode" has been validated by me and found appropriate with mentioned suggestions.

Signature : 

Name : Mrs. Sheila Rosalene.

CERTIFICATE FOR VALIDITY

This is to certify that the project tool on ""A study to evaluate the effectiveness of Apitherapy in reducing oral mucositis among cancer patients undergoing radiation therapy in Selected cancer centers at Erode" has been validated by me and found appropriate with mentioned suggestions.

Signature : P.

Name : Mrs. P. SUMATHI.

CERTIFICATE FOR VALIDITY

This is to certify that the project tool on ""A study to evaluate the effectiveness of Apitherapy in reducing oral mucositis among cancer patients undergoing radiation therapy in Selected cancer centers at Erode" has been validated by me and found appropriate with mentioned suggestions.

Signature :

Name : Mrs. SHOBANA.J

CERTIFICATE FOR VALIDITY

This is to certify that the project tool on ""A study to evaluate the effectiveness of Apitherapy in reducing oral mucositis among cancer patients undergoing radiation therapy in Selected cancer centers at Erode" has been validated by me and found appropriate with mentioned suggestions.

Signature :

CERTIFICATE FOR VALIDITY

This is to certify that the project tool on "A **study to evaluate the effectiveness of Apitherapy in reducing oral mucositis amoang cancer patients under going radiation therapy in Selected Cancer Centre at Erode**

" has been validated by me and found appropriate with mentioned suggestions.

APPENDIX - E

CERTIFICATE OF ENGLISH EDITING

TO WHOM SOEVER IT MAY CONCERN

This is to certify that the dissertation work. "A study to evaluate the

APPENDIX - F

CERTIFICATE OF TAMIL EDITING

TO WHOM SOEVER IT MAY CONCERN

APPENDIX - G

THE COST EFFECTIVENESS OF HONEY

The total amount of honey used for 30 patients for 14 days of interventions is 25 liters, 200 ml. The total cost for the amount of honey spent was Rs. 4,410.

APITHERAPY PROCEDURE

Apitherapy (20ml) of honey orally given to the patients before 15 minutes and after 15 minutes of radiation therapy, ask the patient to swish 20 ml of honey for 5 minutes then swallow it and advise the patients to repeat the same in their homes after 6 hours of radiation treatment.

APPENDIX - H

SECTION A

Demographic variables of head and neck cancer patients undergoing radiation therapy

Please read the following questions carefully and select the answer and place a tick mark (✓) in appropriate space provided on the right side of each question.

1. Age

a) 30-40 years ☐
b) 41- 50 years ☐
c) 51-60 years ☐
d) 61 years and above ☐

2. Sex

a) Male ☐
b) Female ☐

3. Educational status

a) No formal education ☐
b) Primary education ☐
c) High school education ☐
d) Higher secondary education ☐
e) Degree education ☐

4. **Occupation**

a) Coolie ☐
b) House wife ☐
c) Self employee ☐
d) Government employee ☐
e) Unemployee ☐

5. **Marital status**

a) Single ☐
b) Married ☐
c) Widow ☐
d) Divorced ☐

6.**Family monthly income**

a) Rs. 1000- Rs. 3000 ☐
b) Rs.3001- Rs.6000 ☐
c) Rs.6001- Rs.9000 ☐
d) Rs.9001 and above ☐

7. **Area of Residence**

a) Urban ☐
b) Rural ☐

8. **Religion**

a) Hindu ☐
b) Muslim ☐
c) Christian ☐
d) Others ☐

9. **Diagnosis**

a) Oral cancer ☐
b) Tongue cancer ☐
c) Throat cancer ☐
d) Brain cancer ☐

10. **Duration of illness**

a) 0-1 year ☐
b) 2-3 years ☐
c) > 4 years ☐

11. **Duration of treatment**

a) 0-1 year ☐
b) 2-3 years ☐
c) > 4 years ☐

Western Consortium Cancer Nursing Research (WCCNR)
Assessment Scale

Assessment of oral mucositis among head and neck cancer patients Western Consortium Cancer Nursing Research (WCCNR). This scale measures only the anatomical changes associated with oral mucositis.

Grade	0	1	2	3
WCCNR (Western Consortium Cancer Nursing Research)	Lesions: None Colour : pink Bleeding : None	Lesions:1-4 Colour: Slight Red Bleeding: N/A	Lesions:>4 Colour; Moderate Red Bleeding Spontaneous	Lesions: Coalescing Colour: Very Red Bleeding: Spontaneous

Key :-
N/A = Not Applicable
Coalescing = Lesions as a whole

SCORE INTERPRETATION
0 = None,

1 = Mild oral mucositis,

2 = Moderate oral mucositis,

3 = Severe oral mucositis

OBSERVATIONAL CHECK LIST

Please read the following questions carefully and select the answer and a place a tick mark (✓) in appropriate space provided on the right side of each question.

S.NO	QUESTIONS	YES	NO
1.	Do you have difficulty in drinking fluids?		
2.	Do you have difficulty in swallowing solid foods?		
3.	Do you feel any irritation on oral mucosa?		
4.	Are you feeling dryness in the lips?		
5.	Are you feeling any pain inside the mouth ?		
6.	Do you have increase salivation in the mouth?		
7.	Do you have swelling over the gums?		
8.	Are you have bad odor on the mouth?		
9.	Do you have any taste changes in your mouth?		
10.	Do you feel any difficulty while speaking with others?		

SCORE INTERPRETATION:

0 = None

1 - 3 = Mild oral mucositis

4 - 6 = Moderate oral mucositis

7 - 10= Severe oral mucositis

பகுதி - அ

சுய குறிப்புகள்

கீழ்கண்ட வினாக்களை சரியாக படித்து உங்கள் பதில்களை வலது புறமாக கொடுக்கப்பட்டுள்ள கட்டத்தில் குறிப்பிடவும்

1. வயது

அ) 30 - 40 வருடங்கள் ☐

ஆ) 41 - 50 வருடங்கள் ☐

இ) 51 - 60 வருடங்கள் ☐

ஈ) 61 வருடங்கள் மற்றும் அதற்கு மேல் ☐

2. பாலினம்

அ) ஆண் ☐

ஆ) பெண் ☐

3. கல்வித்தகுதி

அ) முறையற்ற கல்வி பயின்றவர் ☐

ஆ) ஆரம்பகல்வி பயின்றவர் ☐

இ) உயர்நிலைக்கல்வி பயின்றவர் ☐

ஈ) மேல்நிலைக்கல்வி பயின்றவர் ☐

உ) பட்டையப்படிப்பு பயின்றவர் ☐

4. தொழில் விபரம்

அ) கூலி வேலை செய்பவர் ☐

ஆ) குடும்ப பெண் ☐

இ) சுய தொழில் செய்பவர் ☐

ஈ) அரசாங்க பணி புரிபவர் ☐

உ) வேலை இல்லாதவர் ☐

5. திருமண விபரம்

அ) திருமணம் ஆகாதவர் ☐

ஆ) திருமணம் ஆனவர் ☐

இ) விதவை ☐

ஈ) விவாகரத்து பெற்றவர் ☐

6. குடும்ப மாதவருமானம்

அ) ரூ. 1000 முதல் ரூ. 3000 வரை ☐

ஆ) ரூ. 3001 முதல் ரூ. 6000 வரை ☐

இ) ரூ. 6001 முதல் ரூ. 9000 வரை ☐

ஈ) ரூ. 9001 மற்றும் அதற்கு மேல் ☐

7. இருப்பிட விபரம்

அ) நகர்புறம் ☐

ஆ) கிராமப்புறம் ☐

8. மதம்

அ) இந்து மதத்தை சார்ந்தவர் ☐

ஆ) இஸ்லாமிய மதத்தை சார்ந்தவர் ☐

இ) கிறுஸ்துவ மதத்தை சார்ந்தவர் ☐

ஈ) பிற மதத்தை சார்ந்தவர் ☐

9. நீங்கள் கீழ்கண்ட எந்த பகுதியில் புற்று நோயால் பாதிக்கப்பட்டுள்ளீர்கள்

அ) வாய்பகுதி புற்று நோய் ☐

ஆ) நாக்குபகுதி புற்று நோய் ☐

இ) தொண்டைபகுதி புற்று நோய் ☐

ஈ) மூளை பகுதி புற்று நோய் ☐

10. **நோயின் காலம்**

அ) 0 - 1 வருடம் ☐

ஆ) 2 - 3 வருடம் ☐

இ) 4 மற்றும் அதற்கு மேற்பட்ட வருடங்கள் ☐

11. **கதிர் வீச்சு சிகிச்சையின் காலம்**

அ) 0 - 1 வருடம் ☐

ஆ) 2 - 3 வருடம் ☐

இ) 4 மற்றும் அதற்கு மேற்பட்ட வருடங்கள் ☐

பகுதி - ஆ

தணிக்கை பட்டியல்

கீழ்க்கண்ட வினாக்களை சரியாக படித்து உங்கள் பதில்களை வலதுபுறமாக கொடுக்கப்பட்ட ஆம் / இல்லை என்ற இடத்தில் குறிப்பிடவும்.

வ. எண்	வினாக்கள்	ஆம்	இல்லை
1.	நீராகாரம் குடிக்கும் போது தொண்டையில் ஏதாவது சிரமமாக இருக்கிறதா?		
2.	திரவ உணவு விழுங்கும் போது தொண்டையில் ஏதாவது சிரமமாக இருக்கிறதா?		
3.	வாயின் உட்பகுதியில் எரிச்சல் ஏற்படுகிறதா?		
4.	உதடுகளில் வறட்சி தன்மை ஏற்படுகிறதா?		
5.	வாயின் உட்பகுதியில் வலி இருப்பது போல் உணர்கிறீர்களா?		
6.	வாயில் துர்நாற்றம் ஏற்படுகிறதா?		
7.	பற்களிலுள்ள ஈறுகளில் வீக்கம் உள்ளதா?		
8.	வாயில் எச்சில் அதிகமாக சுரக்கின்றதா?		
9.	உணவு உட்கொள்ளும் பொழுது சுவை வித்தியாசம் தெரிகிறதா?		
10.	மற்றவரிடத்தில் பேசும் போது ஏதாவது சிரமத்தை உணர்கிறீர்களா?		

மொத்த மதிப்பெண்கள் -10

APPENDIX - I

PHOTOS